



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS-1782-P]

RIN 0938-AV05

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2024. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. This rule also includes requests for information regarding potential changes to the low-volume payment adjustment under the ESRD PPS. In addition, this proposed rule would update requirements for the ESRD Quality Incentive Program and the ESRD Treatment Choices Model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 25, 2023.

ADDRESSES: In commenting, please refer to file code CMS-1782-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1782-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1782-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Drug Add-on Payment Adjustment (TDAPA) or Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

Delia Houseal, (410) 786-2724, for issues related to the ESRD Quality Incentive Program (QIP).

ETC-CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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I. Executive Summary

A. Purpose

This proposed rule proposes updates to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model. Additionally, this proposed rule proposes policies that reflect our commitment to achieving equity in health care for our beneficiaries by supporting our ability to assess whether, and to what extent, our programs and policies perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities. Our policy objectives include its commitment to advancing health equity, which stands as the first pillar of the CMS Strategic Plan,¹ and reflect the goals of the Biden-Harris Administration, as stated in Executive Order 13985.² We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of

¹ Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: <https://www.cms.gov/pillar/health-equity>.

² 86 FR 7009 (January 25, 2021). <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>.

race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.”³ In our CY 2023 ESRD PPS final rule, we noted that, when compared with all Medicare fee-for-service (FFS) beneficiaries, Medicare FFS beneficiaries receiving dialysis are disproportionately young, male, and African-American, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting (87 FR 67183). In this proposed rule, we continue to address health equity for beneficiaries with ESRD who are also members of underserved communities, including but not limited to those living in rural communities, those who have disabilities, and racial and ethnic minorities. The term underserved communities refers to populations sharing a particular characteristic, including geographic communities that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.⁴ Specifically, in this proposed rule, we are requesting information regarding a potential payment adjustment for geographically isolated and rural ESRD facilities, proposing additional payment for the subgroup of Pediatric ESRD Patients (as defined in 42 CFR 413.171), and furthering our efforts to determine if payment to ESRD facilities treating patients with co-morbidities such as sickle cell anemia is aligned with resource use by such ESRD facilities. Additionally, we are proposing to add three new measures to the ESRD QIP measure set that are aimed at promoting health equity for ESRD patients, including by enabling ESRD facilities to identify gaps experienced by their patient populations.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for

³ Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: <https://www.cms.gov/pillar/health-equity>.

⁴ 86 FR 7009 (January 25, 2021). <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>.

Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This proposed rule would update the ESRD PPS for CY 2024.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This proposed rule would update the AKI payment rate for CY 2024.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. This proposed rule proposes several updates for the ESRD QIP, including: a revision to the regulatory definition of “minimum total performance score” that more accurately captures how we calculate the median of national ESRD facility performance on reporting measures; the

codification of our previously finalized measure selection, retention, and removal policies; updates that would begin with Payment Year (PY) 2026, including one new measure, modifications to two current measures, and the removal of two measures; and the addition of two new measures beginning with PY 2027.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center), and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures.

The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled “Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures” (85 FR 61114), referred to herein as the “Specialty Care Models final rule.” We revised and updated certain ETC Model policies in the CY 2022 ESRD PPS final rule (86 FR 61874), and the CY 2023 ESRD PPS final rule (87 FR 67136). In this rule, we are proposing to revise our regulations at 42 CFR 512.390 to acknowledge the availability of administrative review of targeted review requests. This change would provide ETC Participants with information about the availability of administrative review if an ETC Participant wishes to seek additional review of its targeted review request.

B. Summary of the Major Provisions

1. ESRD PPS

- Proposed update to the ESRD PPS base rate for CY 2024: The proposed CY 2024 ESRD PPS base rate is \$269.99, an increase from the CY 2023 ESRD PPS base rate of \$265.57. This proposed amount reflects the application of the proposed combined wage index and transitional pediatric ESRD add-on payment adjustment (TPEAPA) budget-neutrality adjustment factor (0.999652) and a proposed productivity-adjusted market basket percentage increase of

1.7 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling \$269.99 ($(\$265.57 \times 0.999652) \times 1.017 = \269.99).

- Proposed annual update to the wage index: We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2024, we are proposing to update the wage index values based on the latest available data.

- Proposed annual update to the outlier policy: We are proposing to update the outlier policy based on the most current data. Accordingly, we are proposing to update the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2024 using the latest available CY 2022 claims data. We are proposing to update the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2022 claims data, and update the FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021, and CY 2022. For pediatric beneficiaries, the proposed FDL amount would decrease from \$23.29 to \$13.71, and the proposed MAP amount would decrease from \$25.59 to \$24.53, as compared to CY 2023 values. For adult beneficiaries, the proposed FDL amount would increase from \$73.19 to \$78.21, and the proposed MAP amount would decrease from \$39.62 to \$38.58. The 1.0 percent target for outlier payments was not achieved in CY 2022. Outlier payments represented approximately 0.9 percent of total Medicare payments rather than 1.0 percent.

- Proposed update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2024: The proposed CY 2024 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is \$9.96. This offset amount would reflect the application of the proposed ESRD Bundled (ESRDB) market basket update of 1.7 percent ($\$9.79 \times 1.017 = \9.96). There

are no capital-related assets set to receive the TPNIES in CY 2024 for which this offset would apply.

- Proposed clarifications to the TPNIES eligibility criteria: We are proposing certain clarifications regarding our evaluation of the TPNIES eligibility criteria under § 413.236(b).
- TPNIES application received for CY 2024: This proposed rule presents a summary of the one CY 2024 TPNIES application that we received by the February 1, 2023 deadline. This rule also presents our preliminary analysis of the applicant's claims related to substantial clinical improvement (SCI) and other eligibility criteria for the TPNIES.
- Proposed modifications to the administrative process for the low-volume payment adjustment (LVPA): We are proposing to create an exception to the current LVPA attestation process for ESRD facilities that are affected by disasters and other emergencies. This exception would allow ESRD facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA. Additionally, it would allow an ESRD facility to receive the LVPA even if it exceeds the LVPA threshold if its treatment counts increase due to treating additional patients displaced by a disaster or emergency.
- Proposed policy to measure patient-level utilization: We are proposing to require ESRD facilities to report the time on machine (that is, the amount of time that a beneficiary spends receiving an in-center hemodialysis treatment) on claims. We are seeking comment on the proposed effective date of January 1, 2025, given the operational changes needed.
- Proposed Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA): We are proposing to establish and apply a new add-on payment adjustment of 30 percent of the per treatment payment amount to all renal dialysis services furnished to Pediatric ESRD Patients effective January 1, 2024, for CYs 2024, 2025, and 2026. This would serve to bring Medicare payments for renal dialysis services furnished to pediatric patients more in line with their estimated relative costs for the next three years until further collection and analysis of cost report data can be conducted.

- Proposed add-on payment adjustment for after the end of the transitional drug add-on payment adjustment (TDAPA) period: We are proposing a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period, which we would call the post-TDAPA payment adjustment. This payment adjustment would be case-mix adjusted and set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA payment adjustment would be applied to all ESRD PPS payments and paid for 3 years.

- Proposed policy to require reporting of discarded billing units of certain renal dialysis drugs and biological products paid for under the ESRD PPS: We are proposing a new policy to require the use of the JW or JZ modifier on claims to track discarded amounts of single-vial and single-package renal dialysis drugs and biological products paid for under the ESRD PPS.

2. Payment for Renal Dialysis Services Furnished to Individuals with AKI

We are proposing to update the AKI payment rate for CY 2024. The proposed CY 2024 payment rate is \$269.99, which is the same as the ESRD PPS base rate proposed for CY 2024.

3. ESRD QIP

We are proposing several updates for the ESRD QIP. We are proposing to codify the definition of “minimum total performance score” and to codify our previously finalized measure selection, retention, and removal policies. Beginning with PY 2026, we are proposing to add the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set, modify the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) reporting measure to align with updated measure specifications developed by the Centers for Disease Control and Prevention (CDC), remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure, and update the Clinical Depression Screening and Follow-Up measure’s scoring methodology and convert that measure to a clinical measure. Beginning with PY 2027, we are proposing to add the Social

Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set.

4. ETC Model

We are proposing to revise our regulations at § 512.390 to acknowledge the ability of the CMS Administrator to review the results of ETC Participants' targeted review requests.

C. Summary of Costs and Benefits

In section VIII.D.5 of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact table in section VIII.D.5.a of this proposed rule displays the estimated change in Medicare payments to ESRD facilities in CY 2024 compared to estimated Medicare payments in CY 2023. The overall impact of the CY 2024 changes is projected to be a 1.6 percent increase in Medicare payments. Hospital-based ESRD facilities have an estimated 2.6 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 1.6 percent increase. We estimate that the aggregate ESRD PPS expenditures would increase by approximately \$130 million in CY 2024 compared to CY 2023. This reflects a \$140 million increase from the proposed payment rate update, including approximately \$1.7 million in estimated TDAPA payment amounts, as further described in the next paragraph, as well as the proposed post-TDAPA payment amount. We estimate a \$10 million decrease from the proposed outlier payment update. Because of the projected 1.6 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 1.6 percent in CY 2024, which translates to approximately \$30 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment

for certain new renal dialysis drugs and biological products and § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies. The TDAPA and the TPNIES are not budget neutral.

As discussed in section II.D of this proposed rule, the TPNIES payment period for the Tablo® System ends on December 31, 2023. As discussed in section II.E of this proposed rule, the TDAPA payment period for KORSUVA™ (difelikefalin) would continue in CY 2024. We estimate that the overall TDAPA payment amounts in CY 2024 would be approximately \$1.7 million, of which, approximately \$345,000 would be attributed to beneficiary coinsurance amounts.

2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals with AKI

The impact table in section VIII.D.5.c of this proposed rule displays the estimated CY 2024 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2023. The overall impact of the CY 2024 changes is projected to be a 1.6 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities would have an estimated 1.8 percent increase in Medicare payments compared with freestanding ESRD facilities that would have an estimated 1.6 percent increase. The overall impact reflects the effects of the proposed Medicare payment rate update and proposed CY 2024 wage index. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the proposed CY 2024 ESRD PPS base rate, would increase by \$1 million in CY 2024 compared to CY 2023.

3. Impacts of the Proposed Changes to the ESRD QIP

We estimate that the overall economic impact of the PY 2026 ESRD QIP would be approximately \$141.1 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The \$141.1 million estimate for PY 2026 includes

\$121.1 million in costs associated with the collection of information requirements and approximately \$20 million in payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2027 ESRD QIP would be approximately \$148 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The \$148 million estimate for PY 2027 includes \$130.7 million in costs associated with the collection of information requirements and approximately \$17.3 million in payment reductions across all facilities.

4. Impacts of the Proposed Changes to the ETC Model

The impact estimate in section VIII.D.5.d of this proposed rule describes the estimated change in anticipated Medicare program savings arising from the ETC Model over the duration of the ETC Model as a result of the changes in this proposed rule. We estimate that the ETC Model would result in \$28 million in net savings over the 6.5 year duration of the ETC Model. We also estimate that the changes proposed in this proposed rule would produce no change in net savings for the ETC Model. As the ETC Model targeted review process has already been finalized in the Specialty Care Models final rule and ETC Participants are not required to seek administrative review of targeted review determinations, we believe there would be minimal additional burden associated with our proposal.

II. Calendar Year (CY) 2024 End Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable

Care Act), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112-240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized \$29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket percentage increase should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to

January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113-295) amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second payment adjustment reflects differences in area wage levels developed

from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010, in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

We published a final rule, which appeared in the November 7, 2022, issue of the **Federal Register**, titled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,” referred to herein as the “CY 2023 ESRD PPS final rule.” In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2023. We also finalized changes that included rebasing and revising the ESRDB market basket to reflect a 2020 base year, refining the methodology for outlier calculations, implementing a wage index floor of 0.600, implementing a permanent 5 percent cap on year-over-year wage index decreases for

ESRD facilities, and modifying the definition of “oral-only drug.” For further detailed information regarding these updates, see 87 FR 67136.

B. Provisions of the Proposed Rule

1. Proposed CY 2024 ESRD PPS Update

a. Proposed CY 2024 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

(1) Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized a revised and rebased ESRDB input price index to reflect a CY 2020 base year.

Although “market basket” technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost

categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term “ESRDB market basket,” as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

(2) Proposed CY 2024 ESRD Market Basket Update

We propose to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154) to compute the proposed CY 2024 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket percentage increase based on IHS Global Inc.’s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in section II.B.1.a.(2)(c), we are proposing to calculate the market basket update for CY 2024 based on the proposed market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(a) Proposed CY 2024 Market Basket Percentage Increase

Based on IGI’s first quarter 2023 forecast of the 2020-based ESRDB market basket, the proposed CY 2024 market basket percentage increase is 2.0 percent. We also propose that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data, if appropriate, to determine the CY 2024 market basket percentage increase in the final rule.

(b) Proposed Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRDB market basket percentage increase shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the “productivity adjustment”).

The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. As we noted in the CY 2023 ESRD PPS final rule (87 FR 67155), the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term “multifactor productivity” with “total factor productivity” (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology.⁵ As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We referred readers to <https://www.bls.gov/productivity/> for the BLS historical published TFP data. A complete description of IGI’s TFP projection methodology is available on the CMS website at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch>. In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we will be changing the name of this adjustment to refer to it as the productivity adjustment rather than the

⁵ Total Factor Productivity in Major Industries – 2020. Available at: <https://www.bls.gov/news.release/prod5.nr0.htm>.

MFP adjustment. We stated this was not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Based on IGI's first quarter 2023 forecast, the proposed productivity adjustment for CY 2024 (the 10-year moving average of TFP for the period ending CY 2024) is 0.3 percentage point. Furthermore, we propose that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 productivity adjustment in the final rule.

(c) Proposed CY 2024 Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we propose to base the CY 2024 market basket percentage increase on IGI's first quarter 2023 forecast of the 2020-based ESRDB market basket. We propose to then reduce this percentage increase by the estimated productivity adjustment for CY 2024 based on IGI's first quarter 2023 forecast. Therefore, the proposed CY 2024 ESRDB market basket update is equal to 1.7 percent (2.0 percent market basket percentage increase reduced by a 0.3 percentage point productivity adjustment). Furthermore, as noted previously, we propose that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 market basket percentage increase and productivity adjustment in the final rule.

We note that, as discussed in the CY 2023 ESRD PPS final rule (87 FR 67157), many commenters requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate to support ESRD facilities during the inflationary period occurring at that time, particularly accounting for what commenters stated was an error in the forecasted payment updates for CYs 2021 and 2022. In response to those comments, we reminded readers that ESRDB market basket updates are set prospectively, which means that the update relies on a mix

of both historical data for part of the period for which the update is calculated, and forecasted data for the remainder. We explained that while there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase.⁶ We also explained that due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the CY 2017 ESRDB forecast error was -0.8 percentage point, while the CY 2021 ESRDB forecast error was +1.2 percentage point. At the time of the CY 2023 ESRD PPS final rule, CY 2022 historical data was not yet available to calculate a forecast error for CY 2022; however, based on the latest available historical data for CY 2022, we calculate that the CY 2022 ESRDB forecast error was +2.7 percentage point.

As we discussed in the CY 2023 ESRD PPS final rule (87 FR 67156), we recognized that recent higher inflationary trends impacted the outlook for price growth over the next several quarters. For that CY 2023 ESRD PPS final rule, we used an updated forecast of the price proxies underlying the market basket that incorporated more recent historical data and reflected a revised outlook regarding the U.S. economy and expected price inflation for CY 2023 for ESRD facilities. We explained that predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations, and that forecast error calculations are unpredictable (87 FR 67517). Historically, the positive differences between the actual and forecasted market basket increase in prior years have offset negative differences over time. Therefore, in accordance with our longstanding ESRDB market basket update methodology, we are not proposing to apply a forecast error adjustment to the ESRDB market basket update for CY 2024.

(d) Labor-Related Share

⁶ FAQ—Market Basket Definitions and General Information. Available at: [https://www.cms.gov/ Research-Statistics-Data-and-Systems/StatisticsTrends-and-Reports/MedicareProgramRatesStats/ Downloads/info.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/StatisticsTrends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf).

We define the labor-related share as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. For the CY 2024 ESRD PPS payment update, we are proposing to continue using a labor-related share of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

b. Proposed CY 2024 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For

rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We applied the statewide urban average based on the average of all urban areas within the State to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we applied the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are located in Puerto Rico and the US Virgin Islands. However, the wage index floor value is applicable for any area that may fall below the floor. A further description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967) and the CY 2023 ESRD PPS final rule (87 FR 67161).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized a labor-related share of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18-04, beginning with the CY 2021 ESRD PPS wage index. In that same rule, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. For CY 2024, as discussed in

section II.B.1.a.(2)(d) of this proposed rule, the labor-related share to which the wage index would be applied is 55.2 percent.

(2) Proposed CY 2024 ESRD PPS Wage Index

For CY 2024, we propose to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We propose to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2024, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2019, and before October 1, 2020 (Fiscal Year (FY) 2020 cost report data).

For CY 2024, we propose to update the ESRD PPS wage index to use the most recent hospital wage data. We propose that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the wage index), we would use such data, if appropriate, to determine the CY 2024 ESRD PPS wage index in the final rule. The proposed CY 2024 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>. Addendum A provides a crosswalk between the CY 2023 wage index and the proposed CY 2024 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>.

c. Proposed CY 2024 Update to the Outlier Policy

(1) Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some patients require high cost care, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services: (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iv) renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (v) renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.⁷

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the

⁷ Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.⁸ We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based on our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP amount per treatment plus the FDL amount. As described in the following paragraphs, the ESRD facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term "national adjusted average" in this section of this proposed rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient

⁸ Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf>.

characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments. In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We finalized that we would continue to follow our established methodology for the calculation of the adult and pediatric MAP amounts, but we would prospectively calculate the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years.

(2) CY 2024 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2024, we are proposing to update the MAP amounts for adult and pediatric patients using the latest available CY 2022 claims data. We are proposing to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2022 claims

data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021 and CY 2022, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). CY 2022 claims data showed outlier payments represented approximately 0.9 percent of total Medicare payments (87 FR 67172).

The impact of this proposed update is shown in Table 1, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2023 with the updated proposed estimates for this proposed rule. The estimates for the proposed CY 2024 MAP amounts, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2024 prices for ESRD outlier services.

TABLE 1: Outlier Policy: Impact of Proposal to Use Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2023 (based on 2021 data, price inflated to 2023)*		Column II Proposed outlier policy for CY 2024 (based on 2022 data, price inflated to 2024)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	\$24.13	\$41.36	\$23.52	\$40.26
Adjustments				
Standardization for outlier services	1.0819	0.9774	1.0645	0.9777
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$25.59	\$39.62	\$24.53	\$38.58
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$23.29	\$73.19	\$13.71	\$78.21
Patient-month-facilities qualifying for outlier payment	12.90%	5.90%	20.20%	5.10%

*Column I was obtained from Column II of Table 11 from the CY 2023 ESRD PPS final rule (87 FR 67176).

**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2020, 2021, and 2022.

As demonstrated in Table 1, the estimated FDL per treatment that determines the CY 2024 outlier threshold amount for adults (Column II; \$78.21) is higher than that used for the CY 2023 outlier policy (Column I; \$73.19). The higher threshold is accompanied by a decrease in the adjusted average MAP for outlier services from \$39.62 to \$38.58. For pediatric patients,

there is a decrease in the FDL amount from \$23.29 to \$13.71. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from \$25.59 to \$24.53.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2024 would be 5.10 percent for adult patients and 20.20 percent for pediatric patients, based on the 2022 claims data and methodology finalized in the CY 2023 ESRD PPS final rule. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

(3) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1 percent targeted (87 FR 67170 through 67174). Based on the CY 2022 claims, outlier payments represented approximately 0.9 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. However, this is significantly closer to the 1 percent target than the outlier payments based on CY 2021 claims, which represented approximately 0.5 percent of total payments. We believe the update to the outlier MAP and FDL amounts for CY 2024 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us even closer to meeting our 1 percent outlier policy goal, because we would be using more current data for computing the MAP and FDL amounts, which is more reflective of current outlier services utilization rates. We also note that the proposed recalibration of the FDL amounts would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

d. Proposed Impacts to the CY 2024 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2024

We are proposing an ESRD PPS base rate for CY 2024 of \$269.99. This proposed update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2024, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2024 wage index budget-neutrality adjustment factor using treatment counts from the 2022 claims and facility-specific CY 2023 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2023. The total of these payments became

the target amount of expenditures for all ESRD facilities for CY 2024. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2024 ESRD PPS wage index and proposed labor-related share for CY 2024. As discussed in section II.B.1.b of this proposed rule, the proposed ESRD PPS wage index for CY 2024 includes an update to the most recent hospital wage data and continued use of the 2018 OMB delineations. The total of these payments becomes the new CY 2024 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2024 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2024 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The proposed CY 2024 wage index budget-neutrality adjustment factor is 1.000120. This CY 2024 proposed wage index budget-neutrality adjustment factor reflects the impact of all wage index policy changes, including the proposed CY 2024 ESRD PPS wage index and labor-related share.

Proposed TPEAPA Budget-Neutrality Adjustment Factor: As explained in section II.B.1.g.(4) of this proposed rule, we are proposing a new, budget-neutral transitional add-on payment adjustment for pediatric ESRD renal dialysis services, which we would call the TPEAPA. The proposed CY 2024 budget-neutrality adjustment factor for the TPEAPA is 0.999532. The proposed methodology for deriving the budget-neutrality adjustment factor for the TPEAPA is discussed in detail in section II.B.1.g.(4).

Combined Wage Index and TPEAPA Budget-Neutrality Adjustment Factor: For purposes of calculating the ESRD PPS base rate for CY 2024, we are proposing to use one combined budget-neutrality adjustment factor that would include both the proposed wage index budget-neutrality adjustment factor and the proposed TPEAPA budget-neutrality adjustment

factor. The proposed CY 2024 combined wage index and TPEAPA budget neutrality factor is 0.999652 (1.000120×0.999532). This application would yield a proposed CY 2024 ESRD PPS base rate of \$265.48 prior to the application of the proposed CY 2024 market basket update percentage ($\$265.57 \times 0.999652 = \265.48).

Market Basket Update: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase. As discussed previously in section II.B.1.a.(2)(a) of this proposed rule, the latest CY 2024 projection of the ESRDB market basket percentage increase is 2.0 percent. In CY 2024, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously in section II.B.1.a.(2)(b) of this proposed rule, the latest CY 2024 projection of the proposed productivity adjustment is 0.3 percentage point, thus yielding a proposed CY 2024 ESRD market basket update of 1.7 percent for CY 2024. Therefore, the proposed CY 2024 ESRD PPS base rate is \$269.99 ($(\$265.57 \times 0.999652) \times 1.017 = \269.99).

e. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home

dialysis machine that is already in the ESRD PPS base rate. For purposes of this proposed rule, we will refer to this as the “TPNIES offset amount.”

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 calendar years.

There are currently no capital-related assets that are home dialysis machines set to receive TPNIES for CY 2024 as the TPNIES payment period for the Tablo® System ends on December 31, 2023, and the only TPNIES application for CY 2024 is not for a home dialysis machine. However, as required by § 413.236(f)(3)(v), we are proposing to update the TPNIES offset amount annually according to the methodology described above.

The proposed CY 2024 TPNIES offset amount for capital-related assets that are home dialysis machines is \$9.96. As discussed previously in section II.B.1.a.(2)(c) of this proposed rule, the proposed CY 2024 ESRDB market basket update is 1.7 percent (2.0 percent ESRDB market basket percentage increase reduced by 0.3 percentage point productivity adjustment). Applying the proposed update factor of 1.017 to the CY 2023 TPNIES offset amount results in the proposed CY 2024 TPNIES offset amount of \$9.96 ($\$9.79 \times 1.017 = \9.96). We are proposing to update this calculation to use the most recent data available in the CY 2024 ESRD PPS final rule.

f. Proposed Refinement of the Low-Volume Payment Adjustment (LVPA)

(1) Background

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as

defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. Therefore, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities that meet the definition of a low-volume facility. In this section of the proposed rule, we discuss the low-volume payment adjustment (LVPA) under the ESRD PPS, request information from the public regarding the potential changes to LVPA methodology and potentially creating a new geographic-based payment adjustment in the future, and propose certain changes to the existing administrative process for the LVPA.

The current amount of the LVPA is 23.9 percent. In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume and to determine the treatment threshold for those ESRD facilities identified. After consideration of public comments, we established an 18.9 percent adjustment for ESRD facilities that furnish less than 4,000 treatments annually and indicated that this increase to the base rate would encourage small ESRD facilities to continue providing access to care.

In the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed ESRD facilities that met the definition of a low-volume facility under § 413.232(b) as part of the updated regression analysis and found that the ESRD facilities still had higher costs compared to other ESRD facilities. A regression analysis of CYs 2012 and 2013 low-volume facility claims, and cost report data indicated a multiplier of 1.239 percent; therefore, we proposed an updated LVPA adjustment factor of 23.9 percent in the CY 2016 ESRD PPS proposed rule (80 FR 37819) and finalized this policy in the CY 2016 ESRD PPS final rule (80 FR 69001). In CY 2021, 366 ESRD facilities received the LVPA. Using the most recent available data for CY 2022, the number of ESRD facilities receiving the LVPA was 353.

(a) Current LVPA Methodology

Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent, except as specified in paragraph (g)(4)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. In order to receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, “treatments” mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis patients, one week of peritoneal dialysis is considered equivalent to three hemodialysis treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1 deadline for attestation submissions unless extraordinary circumstances justify an exception and specifies exceptions for certain years where the deadline is in December or January. The November 1st attestation timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA payment for all the Medicare-eligible treatments in the payment year. Once an ESRD facility is determined to be eligible for the LVPA, a 23.9 percent increase is applied to the ESRD PPS base rate for all treatments furnished by the ESRD facility (80 FR 69001).

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID-19 Public Health Emergency (PHE). Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we will only consider total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. ESRD facilities that would not otherwise meet the number of treatments criterion because of the COVID-19 PHE may attest that their total dialysis treatments for those 6 months of their cost reporting period ending in 2020 are less than 2,000. The attestation must further include that although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID-19 PHE. MACs will annualize the total dialysis treatments for the total treatments reported in those 6 months by multiplying by 2.

(b) Current Issues and Concerns from Interested Parties

Interested parties, including the Medicare Payment Advisory Commission (MedPAC) and the Government Accountability Office (GAO),⁹ have recommended that we make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas.¹⁰ These groups and other interested parties have also have expressed concern that the strict treatment count introduces a “cliff-effect” that may incentivize ESRD facilities to restrict their patient caseload to remain below the 4,000 treatments per year for the LVPA threshold.¹¹

We considered several changes to the LVPA eligibility criteria to address the concerns that GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. Specifically,

⁹ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.

¹⁰ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

¹¹ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

these interested parties have requested that we take into consideration the geographic isolation of an ESRD facility within the LVPA methodology. Section 1881(b)(14)(D)(iii) of the Act requires that the LVPA must reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. Our analysis has found that isolated low-volume facilities do not face higher costs than other low-volume facilities. Therefore, we do not believe that this requested change reconciles with the central statutory requirements and limitations for the LVPA, and we are considering alternative approaches, including potentially addressing this issue through a new payment adjustment separate from the LVPA based on section 1881(b)(14)(D)(iv) of the Act. Currently, we are analyzing claims and cost data regarding dialysis treatment levels and cost to inform options for potentially tailoring our methodology to meet the requirements of the statute, while simultaneously collecting additional data on geographic isolation of ESRD facilities. The ESRD PPS has separate facility-level payment adjustments for low-volume facilities, as set forth in 42 CFR 413.232, and facilities in rural areas, as set forth in 42 CFR 413.233. To avoid overlap with these existing facility-level adjustments, we are analyzing the impact of potentially creating a new payment adjustment and considering innovative methodological options, such as the local dialysis need methodology on which we are requesting information in section II.B.1.f.(2)(b) of this proposed rule.

In addition, we have heard from interested parties that the eligibility criteria for the LVPA are very explicit and leave little room for flexibility in certain circumstances (85 FR 71442). Some also view the attestation process as burdensome to ESRD facilities and believe it may discourage participation by small ESRD facilities with limited resources that would otherwise qualify for the LVPA.¹² Given these concerns, we have considered alternative

¹² <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

approaches to the LVPA that would reduce burden, remove negative incentives that may result in gaming, and better target ESRD facilities that are critical for beneficiary access.

CMS's contractor has held three Technical Expert Panels (TEPs) to discuss potential refinements to the ESRD PPS.¹³ During the 2018, 2019, and 2020 TEPs, panelists, including representatives from ESRD facilities, independent researchers, patient advocates, and representatives from professional associations and industry groups (86 FR 36397), discussed limitations of the current LVPA methodology and potential alternatives. In the CY 2022 ESRD PPS proposed rule, we included a request for information (RFI) to inform LVPA payment reform (86 FR 36398 through 36399). All fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural adjustment.¹⁴ One small dialysis organization within a large non-profit health system responded that it is reliant upon the LVPA and the rural adjustment and supports both adjustments, albeit with modifications. MedPAC renewed its support for a new Low-Volume and Isolated (LVI) adjustment with a three-tiered approach for treatment thresholds, which would incorporate geographic isolation into its methodology and may disincentivize gaming. MedPAC called upon CMS to provide clear and timely criteria for ESRD facility eligibility and ensure the LVPA methodology is transparent. In concurrence with MedPAC, a coalition of dialysis organizations, three large dialysis organizations (LDOs), a non-profit kidney organization, and a provider advocacy coalition commented that the rural adjustment should be eliminated and an LVI methodology should be adopted, as they considered a methodology based upon census tracts to be both complicated and lacking transparency. Numerous commenters wrote in support of a tiered adjustment to mitigate the cliff effect and gaming. Commenters raised concerns regarding the census tract methodology's reliance upon 'driving time' as a data measure, noting this presents legitimate equity issues. Those who have relied upon both the LVPA and rural payment

¹³ https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.

¹⁴ <https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf>.

adjustments to remain operational expressed opposition to elimination of either adjustment. The materials from the TEPs and summary reports can be found at https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources. For this proposed rule, we considered the above-referenced input from interested parties and subsequent data obtained to inform the RFIs below.

(2) Requests for Information on Modification of LVPA Methodology and Development of a New Payment Adjustment Based on Geographic Isolation

As discussed in the previous section, we recognize the importance of revising the ESRD PPS LVPA adjustment methodology to ensure that payments accurately reflect differences in cost and adequately target low-volume facilities, and to strive for healthcare equity for ESRD beneficiaries. The LVPA and rural adjusters currently result in increased payments to some geographically isolated ESRD facilities, but these adjusters do not specifically target geographically isolated ESRD facilities. We noted several points of concern that interested parties have raised in the past, as well as certain statutory limitations that could apply to some of the methodological approaches suggested in the past. We are seeking information from the public about potential approaches to refine the ESRD PPS methodology, which we would take into consideration for any potential changes to the LVPA in the future.

This section addresses several RFIs regarding the LVPA and a potential new adjustment for geographically isolated ESRD facilities. Upon reviewing the RFIs, respondents are encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; RFIs do not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the United States (U.S.) Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs

incurred in response to this RFI; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted.

Please note that we will not respond to questions about the policy issues raised in these RFIs. We may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained because of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become U.S. Government property and will not be returned. We may publicly post the comments received, or a summary thereof.

(a) Comment Solicitation for Modifications to LVPA Methodology

We are soliciting comment on potential changes to the LVPA methodology, including maintaining a single threshold, establishing LVPA tiers, and/or utilizing a continuous function. Any potential refinements to the LVPA methodology that may result from our consideration of these comments would be proposed through notice-and-comment rulemaking in the future. We request that commenters keep in mind that section 1881(b)(14)(D)(iii) of the Act requires the LVPA to reflect the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services.

(i) Maintain a Single LVPA Threshold

As discussions about modifying the existing treatment threshold or payment adjustment percentage have been ongoing since the beginning of the multi-year LVPA reform efforts, we are soliciting comments on maintaining a single threshold for the LVPA. ESRD facilities that fall below the treatment threshold would continue to receive payment, and payments would not be adjusted for those ESRD facilities above the threshold. We are engaged in continuing

monitoring efforts to align resource use with payment. If we were to re-compute the LVPA percentage amount using the latest available claims and cost report data and the methodology established in the CY 2011 and CY 2016 ESRD PPS final rules (75 FR 49118 through 49125 and 80 FR 69001), the current treatment threshold of 4,000 treatments per year would correspond to a 17.6 percent payment adjustment. The 4,000-treatment threshold could be maintained, or the treatment threshold could be recalibrated to maintain the 23.9 percent payment adjustment. Maintaining a single threshold would not address concerns regarding the potential for gaming or remove what commenters call the payment cliff. Potential approaches for a single LVPA threshold are outlined below in Table 2.

TABLE 2: Potential Approaches for a Single LVPA Threshold

Option	Description
Status quo	4,000-treatment threshold with 23.9 percent payment adjuster
Maintain Treatment Threshold	4,000-treatment threshold with 17.6 percent payment adjuster
Maintain Payment Adjuster	Reduce treatment threshold to 3,750 treatments to maintain 23.9 percent payment adjuster

(ii) Establishment of Multiple LVPA Tiers

We are soliciting comment on creating a tiered payment adjustment that would include multiple thresholds, with separate payment adjustments calibrated so that ESRD facilities in tiers with the lowest treatment volume would receive the highest payment adjustment, and vice versa. MedPAC has previously recommended setting LVPA treatment thresholds at fewer than 4,000 treatments, between 4,000 and 4,999 treatments, and between 5,000 and 6,000 treatments, with payment adjustments calibrated so that ESRD facilities in tiers with the lowest volume would receive the highest payment adjustment, and vice versa.¹⁵ Establishing multiple

¹⁵ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.

thresholds, with a separate payment adjustment for ESRD facilities under each threshold level, would reduce the potential for gaming through reduction of the magnitude of the payment cliff. Additionally, LVPA eligibility would be expanded to more ESRD facilities. We are soliciting comments regarding establishment of multiple thresholds, including up to an eight-tiered structure for the LVPA. Tables 3 through 6 outline various methodological options. Tables 3 through 4 would establish larger adjustment factors on average than the current methodology, but would require reductions to the ESRD PPS base rate to maintain budget neutrality. Tables 5 through 6 show adjustment factors which are scaled to maintain budget neutrality within the LVPA, keeping the LVPA's budget at the same amount that would occur under the current methodology without requiring reductions to the ESRD PPS base rate. As illustrated below, scaling the adjusters while maintaining budget neutrality within the LVPA results in lower LVPA adjusters. For example, Tier 1 (less than 5,000 treatments) in the Four-Tiered Model varies based on the approach to maintaining budget neutrality, as the LVPA adjuster is 13.7 percent where budget neutrality is maintained within the ESRD PPS (Table 3) and 5.8 percent where budget neutrality is maintained within the LVPA (Table 5). For comparison, the Eight-Tiered Model shows that for Tier 1 (less than 1,000 treatments), ESRD facilities would receive a 123 percent LVPA adjuster where budget neutrality is maintained within the ESRD PPS (Table 4) and 40.5 percent LVPA adjuster where budget neutrality is maintained within the LVPA (Table 6).

TABLE 3: LVPA Adjustment with Four Tiers (\$1.20 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	LVPA Adjusters
Tier 1 (less than 5,000)	13.7%
Tier 2 (5,000 – 5,999)	8.4%
Tier 3 (6,000 – 6,999)	4.7%
Tier 4 (7,000 – 7,999)	1.9%

TABLE 4: LVPA Adjustment with Eight Tiers (\$1.80 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	LVPA Adjusters
Tier 1 (less than 1,000)	123.0%
Tier 2 (1,000- 1,999)	57.6%
Tier 3 (2,000-2,999)	33.9%
Tier 4 (3,000-3,999)	21.4%
Tier 5 (4,000 – 4,999)	13.7%
Tier 6 (5,000 – 5,999)	8.4%
Tier 7 (6,000 – 6,999)	4.7%
Tier 8 (7,000 – 7,999)	1.9%

TABLE 5: LVPA Adjustment with Four Tiers (Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	LVPA Adjuster	Est. Facilities Receiving Adjustment
Tier 1 (less than 5,000)	5.8%	767
Tier 2 (5,000 – 5,999)	3.6%	331
Tier 3 (6,000 – 6,999)	2.0%	332
Tier 4 (7,000 – 7,999)	0.8%	318

TABLE 6: LVPA Adjustment with Eight Tiers (Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	LVPA Adjuster	Est. Facilities Receiving Adjustment
Tier 1 (less than 1,000)	40.5%	22
Tier 2 (1,000- 1,999)	19.0%	69
Tier 3 (2,000-2,999)	11.2%	137
Tier 4 (3,000-3,999)	7.1%	250
Tier 5 (4,000 – 4,999)	4.5%	290
Tier 6 (5,000 – 5,999)	2.8%	331
Tier 7 (6,000 – 6,999)	1.5%	332
Tier 8 (7,000 – 7,999)	0.6%	318

(iii) Continuous Function

We are also soliciting comments on potentially establishing a continuous function to adjust LVPA payments. Under this approach, ESRD facilities with the lowest volume would receive the highest payment adjustment, and the payment adjustment would decrease continuously as volume increases. This could include calibration of the point at which the payment adjustment becomes zero to correspond with the existing 4,000 treatment upper bound, or establishment of a new upper bound based on a regression analysis. Establishment of a continuous function has the potential to significantly reduce the potential for gaming by eliminating payment cliffs entirely. Additionally, this would increase payment for ESRD facilities with the lowest volume, therefore better aligning payment with resource use. Furthermore, a continuous function would potentially expand LVPA eligibility to the most ESRD facilities.

CMS is considering several approaches to modifying the LVPA to address concerns about its incentive structure, treatment threshold, and administrative burden, as expressed by interested parties (including the GAO, MedPAC, and industry representatives). We are issuing this RFI to seek feedback on the suggested changes to the LVPA, as described above, and to solicit further input from interested parties to inform future modifications to the methodology used to determine the LVPA.

In particular, CMS seeks input and responses to the following considerations, requests and questions:

- Regarding concerns about a payment cliff in the existing LVPA, we are considering implementing payment tiers or a continuous adjustment, based on treatment volume, in place of the current single tiered adjustment.

++ Please comment on which payment structure would be more appropriate: single threshold as currently employed, tiered structure, or continuous function, and provide the reasoning behind your recommendation.

++ Please also comment on which option would be most effective in removing gaming incentives and which option would bring greater congruency between cost of providing renal dialysis services and payment.

- Using the alternative methodology described above, under a tiered or continuous payment adjustment, the treatment threshold for eligibility would be determined based on the median treatment count among all ESRD facilities (approximately eight thousand treatments per year). The resulting tiers and incremental payment adjustments between tiers could follow several different configurations.

++ What factors should be evaluated to best determine the treatment count threshold, as well as the tiering structure? Specifically, comment on the treatment volume beneath which per-treatment costs begin to increase.

++ Please enumerate any concerns you might have should the implementation of a tiered or continuous adjustment result in an expanded set of eligible ESRD facilities, and payment redistribution.

- Interested parties have voiced concern regarding the administrative burden involved in the current LVPA attestation process. As such, we are considering potentially decreasing the number of years of attestation data needed to determine LVPA eligibility.

++ Please comment on the extent to which this change would alleviate burden, and if there are other administrative changes that could be made to simplify this process.

++ Please describe any anticipated effects of decreasing the amount of treatment volume data used to determine LVPA eligibility.

++ Please describe the ways that simplifying the attestation process could help ESRD facilities with fewer resources to promote health equity by improving their ability to serve vulnerable and underserved communities.

(b) Comment Solicitation on the Development of a New Payment Adjustment Based on Geographic Isolation

CMS is striving to promote health equity by ensuring that ESRD facilities, including both rural and low-volume facilities, are being paid equitably for serving populations that are currently underserved. We are therefore soliciting comments on potentially assisting geographically isolated ESRD facilities and promoting access in these areas, including labor force hiring and retention. We are considering establishing a new payment adjustment that accounts for isolation, rurality, and other geographical factors. We are also requesting information on geographic isolation to determine if ESRD facilities that are currently considered rural would benefit from a geographic isolation adjustment. The new geographically based payment adjustment may consider local dialysis need (LDN), as explained later in this section, instead of basing payment strictly upon a rural designation, as set forth in §§ 413.233 and 413.231(b)(2). We considered changes to the eligibility criteria to address the concerns that GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are not located near other ESRD facilities that are necessary to protect access to care. As noted above, under section 1881(b)(14)(D)(iii) of the Act, the LVPA must reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. Our preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas *did not* have higher costs than low-volume ESRD facilities overall. Therefore, certain changes that interested parties have suggested would not comport with the statutory requirements and limitations for the LVPA. We are soliciting comments on potential methodologies for creating a separate payment adjustment that could potentially address GAO and MedPAC's concerns, relying upon the authority under section 1881(b)(14)(D)(iv) of the Act, which states that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate.

During the 2020 ESRD PPS TEP, panelists discussed the alternatives to the current LVPA set forth below.¹⁶ One methodology involved utilization of census tracts to identify geographic areas with low demand, which suggested increased beneficiary access by incentivizing dialysis organizations to continue operating ESRD facilities in otherwise non-viable locations. An advantage to this approach would be identifying geographical areas, specifically census tracts, with low demand for dialysis. The TEP participants discussed that the identification of low demand for dialysis would improve targeting to ESRD facilities that are in isolated areas that ESRD beneficiaries travel far to access. Additionally, this would incentivize ESRD facilities to locate in underserved areas that are isolated and rural, promoting access to care for these disadvantaged populations. This methodology aligns with the methodology presented in the TEPs and in the CY 2022 ESRD PPS proposed rule (86 FR 36396 through 36399).

CMS's preliminary analysis has shown that models based on this local dialysis need (LDN) methodology would often result in the ESRD facilities receiving the LDN payment adjustment (that is, ESRD facilities in geographic areas with low LDN) being the only dialysis provider for a number of miles. Additionally, our analysis shows that ESRD facilities receiving the LDN payment adjustment often would be located in a census tract that intersects with areas designated as Health Professional Shortage Areas (HPSAs). The methodology would involve dividing the U.S. into geographic areas based on a reasonable assessment of ESRD beneficiaries' ability or willingness to travel. Regarding interested parties' concerns that previous measures for travel time relied upon beneficiaries' access to a private vehicle (which many beneficiaries may lack), in collaboration with our data contractor, CMS has performed additional analysis regarding the travel time metric to include realized travel time between ESRD facilities and population centers of census tracts, instead of ESRD facilities and patient address. Sensitivity

¹⁶ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf>.

checks have shown that the exact location of patients with ESRD is not essential for accurately determining the LDN of census tracts. Latent demand is then calculated by counting the number of beneficiaries with ESRD near each ESRD facility. “Near” is defined by driving time to ESRD facilities. Latent demand is calculated by multiplying the number of beneficiaries near an ESRD facility by average number of treatments for ESRD beneficiaries. The threshold is then applied by determining the threshold of adjusted latent demand. That is, those ESRD facilities, which fall below the threshold are eligible.

We are considering approaches to implementing an additional payment adjustment for ESRD facilities operating in areas with low LDN/demand. The purpose of this RFI is to seek feedback on the approach described above and to solicit information from interested parties to inform the approach taken to implement this adjustment. Any new payment adjustment of this nature would be proposed through future notice-and-comment rulemaking.

In particular, we seek responses to the following questions.

- What factors should be considered in formulating a payment adjustment for ESRD facilities in isolated geographical areas or areas for which there is a low need for renal dialysis services?
- What are the best ways to incentivize renal dialysis service provision in isolated geographic areas?
- Our analysis of the LDN methodology has shown that low LDN census tracts intersect with areas designated as HPSAs. What impact would a payment adjustment based on geographic isolation have on the ability of ESRD facilities in isolated areas to recruit and retain health care professionals?
- Please comment on the appropriateness of maintaining the rural facility adjustment under § 413.233, if we were to establish an LDN payment adjustment in conjunction with a modified LVPA.

- Please comment on the relationship between geographic isolation and cost. Please provide any data that could further inform CMS’s understanding of the relationship between geographic isolation and cost for low volume facilities.

- Please comment on the appropriateness of utilizing driving time between current beneficiary address and treatment location as the appropriate metric for travel time.

- Are there ways in which the suggested methodology for this potential payment adjustment could fail in targeting isolated ESRD facilities, or ESRD facilities in areas with low LDN?

- Are there ways in which the determination of LDN might be subject to gaming?

- Would a payment adjustment for ESRD facilities in areas with low LDN improve health equity? Are there specific recommendations to change the LDN methodology described above to promote quality access to care for all ESRD beneficiaries?

- Please comment on the favorability of CMS’s implementation of a new payment adjustment for ESRD facilities in areas with low LDN as described above.

- Are there any other considerations we should keep in mind when considering proposing a new payment adjustment based on an LDN methodology?

(3) Proposal for an Exception to the Current LVPA Attestation Process for Disasters and Other Emergencies

Under our current regulations at 42 CFR 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation—(1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in § 413.232(g)(4)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. When we first established these

requirements in the CY 2011 ESRD PPS final rule, we explained that looking across data for three years provided us with a sufficient information to view consistency in business operations (79 FR 49123). In the CY 2019 ESRD PPS final rule (83 FR 56949) and the CY 2021 ESRD PPS proposed rule (85 FR 42165), we acknowledged commenters' concerns that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility during disasters or other emergency situations like the COVID-19 PHE. Commenters have emphasized that low-volume facilities rely on the LVPA, and that loss of the payment adjustment could result in beneficiary access issues.

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42165), the COVID-19 PHE caused ESRD facilities to have to shift patients among ESRD facilities in order to provide uninterrupted care to their Medicare ESRD population. In some cases, this patient shifting increased dialysis treatments at some low-volume ESRD facilities, putting the ESRD facility temporarily over the LVPA treatment threshold. This increase in dialysis treatments, resulting from the PHE, disqualified some ESRD facilities that would have otherwise received the LVPA of 23.9 percent per treatment. In the CY 2021 ESRD PPS final rule (85 FR 71485), we established a policy that ESRD facilities would be held harmless from increases in treatment counts due to temporary patient shifting because of the PHE. To be held harmless, ESRD facilities must follow the attestation process for the exception set forth in § 413.232(g)(4) and are expected to provide supporting documentation to the MACs upon request. Interested parties have expressed support for CMS's swift response to the COVID-19 PHE's impact on ESRD facilities, with an association of dialysis providers stating that holding harmless LVPA status for these ESRD facilities will better ensure that ESRD patients can continue to access the life-sustaining dialysis treatment they need, particularly in rural and underserved areas where low-volume facilities heavily depend on the LVPA to remain open and provide treatment for patients.

We recognize there could be future circumstances, potentially similar to the circumstances of the COVID-19 PHE, in which it would be appropriate to provide flexibilities

with respect to certain LVPA requirements. Commenters have previously expressed concerns about the strict attestation requirements for ESRD facilities to remain eligible for the LVPA, particularly when faced with a disaster or other emergency, such as a local or national emergency, natural disaster, catastrophic event, or public health emergency. We recognize that during disasters or other emergencies, low-volume facilities could be forced to close, or could experience increases in their treatment counts if they treat patients who are displaced from a nearby ESRD facility that is impacted by such an event. For example, in August of 2021, an ESRD facility in Louisiana sustained significant damage as a result of Hurricane Ida, which required the ESRD facility to close for repairs and temporarily stop furnishing renal dialysis services. The ESRD facility served a rural community and for over 10 years received the LVPA due to the low number of dialysis treatments it furnished each year. This ESRD facility sought recourse to maintain its eligibility for the LVPA when it resumed operations following the required repairs to the ESRD facility, however, recourse was unavailable due to the limitations set forth in 42 CFR 413.232(b). When we established the LVPA in the CY 2011 ESRD PPS final rule, we stated that we believed the LVPA should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic (75 FR 49118). Given that these requirements for low-volume facilities were created to protect access to care for the vulnerable patient population that these ESRD facilities serve, adding certain flexibilities during disasters or other emergencies would promote our commitment to ensuring access to care for ESRD patients.

(a) Proposed Changes to the LVPA

We are proposing to make two changes to the LVPA regulation at § 413.232 to allow for more administrative flexibilities during disasters or other emergencies. First, we are proposing to create a new exception to the attestation process for disasters and other emergencies. Second, we are proposing to establish a process that would allow low-volume facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA. CMS would

assess whether a particular situation is a disaster or other emergency based on the totality of the circumstances that could result in disruption of or inability to furnish renal dialysis services at one or more ESRD facilities, thus affecting the ESRD facility's or facilities' ability to qualify for the LVPA. For purposes of this proposal, disasters or other emergencies would include, but not be limited to, the below examples:

- A public health emergency declared by the Secretary due to a significant outbreak of infectious disease or bioterrorist attacks.
- Natural disasters including winter storms, floods, tornados, hurricanes, wildfires, earthquakes, or any combination thereof.¹⁷
- Catastrophic events outside of an ESRD facility's control that disrupt operations and result in an ESRD facility's closure, for example, loss of operations or patient shifting due to a local emergency such as fire, floods, earthquakes, or tornadoes, or
- Other disaster or emergency conditions under which a waiver could be granted pursuant to section 1135 of the Act.

CMS believes these proposed policy changes could help displaced ESRD patients maintain access to renal dialysis services by preventing ESRD facilities from permanently closing due to the loss of their LVPA. It is important that ESRD facilities that are receiving the LVPA are able to maintain LVPA eligibility despite the impacts caused by a disaster or other emergency. The proposed policy could potentially protect other ESRD facilities that need to maintain the LVPA in order to remain open from potentially losing their LVPA by exceeding the treatment threshold because they accepted displaced patients. We do not want the fear of losing the LVPA due to increased treatments exceeding the threshold to disincentivize ESRD facilities from accepting patients from other ESRD facilities experiencing a disaster or other emergency. It is also important that ESRD facilities that are forced to close due to a disaster or other emergency are able to maintain their LVPA eligibility upon reopening to ensure continued

¹⁷ <https://www.dhs.gov/natural-disasters>.

access in areas that otherwise may lack sufficient ESRD facilities. The policy could also help those ESRD facilities affected by the disaster or other emergency potentially resume operations and avoid permanent closure if they would be allowed to receive the LVPA upon reopening despite the closure or disruption of operations.

(i) Proposed Exception to the LVPA Treatment Threshold for ESRD Facilities that Accept Patients from an ESRD Facility Affected by a Disaster or Other Emergency

We are proposing to create an exception to the LVPA treatment threshold requirements set forth in 42 CFR 413.232(b)(1) under a new provision in § 413.232(g)(5), which would allow an ESRD facility to receive the LVPA even if it exceeds the LVPA threshold if its treatment counts increase due to treating additional patients displaced by a disaster or other emergency. Qualification for the proposed exception would require an ESRD facility to absorb those displaced patients from an outside or adjacent ESRD facility that experienced a temporary closure or operational disruption (such as a water shut off). If an ESRD facility accepts the patients of the ESRD facility affected by the disaster or other emergency, causing that ESRD facility to meet or exceed the 4,000-treatment count for all dialysis patients, it would attest to its MAC that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility due to a disaster or other emergency. We are proposing to define temporary patient-shifting in the context of the LVPA in the ESRD PPS as providing renal dialysis services to one or more patient(s) at any time through the end of the calendar year following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to the displaced patient(s). The ESRD facility would be required to request this exception from CMS by writing to the ESRD Payment Mailbox ESRDPAYMENT@cms.hhs.gov no later than the annual attestation deadline of November 1st. CMS would review the exception request within 30 days to determine if the ESRD facility qualifies for the exception. If approved by CMS, the ESRD facility would be paid the LVPA for Medicare beneficiaries for up to the first 4,000 dialysis

treatments in the payment year in which the temporary patient-shifting occurred. Under this proposed exception, the ESRD facility would be held harmless for meeting or exceeding the 4,000 dialysis treatment threshold during one or more cost reporting years within the 3-year lookback for LVPA eligibility as long as their 4,000 dialysis treatment threshold was exceeded as a result of temporary patient-shifting from the ESRD facility that experienced the disaster or other emergency. If CMS does not approve the request, CMS would notify the ESRD facility and the MAC, and the ESRD facility would be disqualified from receiving the LVPA until it meets all the LVPA criteria (including the 3-year lookback). Under this proposal, the ESRD facility receiving this exception must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that previously treated those patients and closed or experienced an operational disruption due to a disaster or other emergency and must provide such documentation to CMS and the MAC upon request. The ESRD facility requesting this exception would have to repeat the process for requesting an exception for each cost reporting year in which its treatment volume meets or exceeds 4,000 due to temporary patient-shifting from the ESRD facility that experienced the disaster or other emergency. Additionally, the ESRD facility requesting this exception would have to follow the attestation process as described at § 413.232(e) for the two payment years following the last cost reporting year in which its treatment volume meets or exceeds 4,000 due to treating displaced patients from the ESRD facility that experienced the disaster or other emergency and attest that the ESRD facility meets the criterion established at § 413.232.

As an example: If a disaster occurs on June 1, 2024, which results in ESRD facility X's closure or operational disruption resulting in ESRD facility Y (an existing low-volume facility) treating additional patients from ESRD facility X that puts ESRD facility Y's total renal dialysis treatments for cost reporting year 2024 over the 4,000 treatment threshold, ESRD facility Y would be required to request an exception to § 413.232(b)(1) from CMS by November 1, 2024 in order to continue receiving the LVPA. Since ESRD facility Y began treating the displaced

patients in CY 2024, the window for temporary patient shifting would extend until December 31, 2025. To be approved for the exception under the new provision in § 413.232(g)(5), CMS would determine that ESRD facility Y furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of ESRD facility X resulting from a disaster or other emergency. Should the exception be approved by CMS, ESRD facility Y would receive the LVPA for up to the first 4,000 treatments it furnished in 2024. Additionally, ESRD facility Y would not be disqualified from receiving the LVPA for PY 2025 and PY 2026 due to exceeding the treatment volume threshold in cost reporting year 2024, assuming the temporary patient-shifting from ESRD facility X occurred only in cost reporting year 2024. For PY 2025 and PY 2026 ESRD facility Y would have to attest that it meets all the criterion for the LVPA because it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency and received an exception for cost reporting year 2024. This would be the same attestation process as if ESRD facility Y did not furnish any excess treatments and was attesting that it continued to meet the criteria for the LVPA for those payment years. If the closure or operational disruption of ESRD facility X causes the treatment volume for ESRD facility Y to meet or exceed the 4,000 dialysis treatment threshold in cost reporting year 2025, ESRD facility Y would have to submit another request for an exception by November 1, 2025. Should this exception be approved, ESRD facility Y would receive the LVPA for up to the first 4,000 treatments it furnished in cost reporting year 2025 and would not be disqualified from receiving the LVPA for payment year 2026 and payment year 2027 due to exceeding the treatment volume threshold in cost reporting year 2024 and cost reporting year 2025. If ESRD facility Y continued to treat displaced patients from ESRD facility X in cost reporting year CY 2026, it would only be considered temporary patient-shifting if ESRD facility Y treated those patients before January 1 2026, and if patients treated after January 1 2026 cause ESRD

facility Y to exceed the 4,000-treatment volume threshold in cost reporting year 2026 then the ESRD facility would be disqualified from receiving the LVPA under § 413.232(b)(1). Under this example, ESRD facility Y would still have to meet the other eligibility requirements to receive the LVPA in any PY in which the ESRD facility would receive the LVPA.

(ii) Proposed Exception to the LVPA Closure Provision for ESRD Facilities Affected by a Disaster or Other Emergency

In addition to proposing an exception to the treatment threshold requirement under § 413.232(b)(1) and (g)(5), we are proposing an exception under § 413.232(g)(6) that would allow an ESRD facility to still receive the LVPA if it temporarily closes. That is, if an ESRD facility temporarily ceases to operate and the patients must go to another ESRD facility to receive renal dialysis services due to a disaster or other emergency, and the ESRD facility subsequently reopens, we are proposing to create an exception to the requirement in § 413.232(b)(2) that an ESRD facility “has not opened, closed, or received a new provider number” in the 3 cost reporting years preceding the payment year. If an ESRD facility is affected by a disaster or other emergency and the ESRD facility is forced to close and re-open later, the ESRD facility would need to request an exception from CMS in writing at the ESRD Payment Mailbox at ESRDPAYMENT@cms.hhs.gov within 60 days of the closure and inform the MAC of the request. CMS would review the request within 30 days of receipt and either approve the request based on a determination that the ESRD facility closed or experienced an operational disruption due to a disaster or other emergency, or deny the request, and would inform both the ESRD facility and the MAC of its decision.

Upon reopening and providing renal dialysis services, the ESRD facility would be required to notify CMS and the MAC in writing within 30 days of its reopening. CMS would acknowledge receipt of the written notification within 30 days. If the exception is approved and CMS is duly informed of the ESRD facility’s reopening, the ESRD facility would remain eligible for the LVPA and the MAC would process payment accordingly. In order to continue

receiving the LVPA the ESRD facility would still have to meet all the other eligibility requirements for the LVPA. The exception to § 413.232(b)(2) would be applicable for a period of 2 cost reporting years following the date of closure of the ESRD facility. After the 2 cost reporting year period the ESRD facility would follow the normal attestation process for the LVPA specified in paragraphs (e) and (g) of § 413.232. The ESRD facility would be required to maintain documentation regarding its closure, and to provide such supporting documentation to CMS and/or the MAC upon request.

For example, if a disaster occurs on June 1, 2024, which results in an ESRD facility experiencing a closure, the ESRD facility would request an exception to § 413.232(b)(2) from CMS within 60 days of June 1, 2024 (that is, on or before July 31, 2024). CMS would review the request and notify the ESRD facility and the MAC within 30 days if the exception is approved or denied. If the ESRD facility then reopens on September 1, 2024, the ESRD facility would notify CMS and the MAC in writing within 30 days of reopening (that is, on or before October 1, 2024). CMS would notify the ESRD facility and the MAC of its receipt of the reopening notification within 30 days. If the exception was approved by CMS, the ESRD facility would remain eligible for the LVPA for the rest of payment year 2024 and for the entirety of payment year 2025 and payment year 2026, provided the ESRD facility continues to meet the other eligibility requirements for the LVPA.

(4) Proposed Technical Correction to 42 CFR 413.232(g)

We are proposing a technical correction at § 413.232(g) to replace “their” with “its,” to clarify the regulation language.

g. Proposed Transitional Pediatric ESRD Add-on Payment Adjustment for Pediatric Patients with ESRD Receiving Renal Dialysis Services

(1) Background

Section 1881(b)(14)(D)(iv)(I) of the Act provides that the ESRD PPS may include such payment adjustments as the Secretary determines appropriate, including a payment adjustment

for pediatric providers of services and renal dialysis facilities. Determining such a payment adjustment has been historically difficult due to the consistent lack of data. The Medicare pediatric ESRD patient population receiving dialysis is small compared to the adult ESRD population, representing approximately 0.14 percent of the total ESRD patient population in 2022. In the past, CMS has considered various different payment adjustments for pediatric patients with ESRD, including different Medicare payments by sex or comorbidities (74 FR 49984 through 49986). However, many of these considered adjustments were not used as we were unable to get acceptable precision due to the small sample size of pediatric patients with ESRD.

Prior to the establishment of the ESRD PPS, payment for pediatric ESRD dialysis services was generally the same rate as adult ESRD dialysis, unless the ESRD facility qualified for an exception to the composite rate. Section 1881(b)(7) of the Act stated that, subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554) (BIPA), the Secretary shall provide for exceptions as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). During this time period, CMS received many comments and concerns regarding the payment rate for renal dialysis services furnished to pediatric patients with ESRD. Section 623(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) later amended section 422(a)(2) of BIPA to provide that any pediatric ESRD facility would be eligible for an exception to the composite rate, effective October 1, 2002. This statute defined pediatric ESRD facilities as facilities with at least 50 percent patients under the age of 18. This enabled pediatric ESRD facilities to obtain payments that specifically recognized the higher cost associated with treating these patients (69 FR 47530).

We finalized a basic case-mix adjustment to the composite payment rate in the CY 2005 Physician Fee Schedule (PFS) final rule published on November 15, 2004 (69 FR 66327). This

included a 62 percent pediatric payment increase (that is, an adjustment factor of 1.62) applied to the composite payment rate per treatment for any facility when furnishing outpatient dialysis services to pediatric patients with ESRD. This factor was derived from the average exception amounts for 20 ESRD facilities that had received exceptions for pediatric patients. This was intended to be a temporary measure, which would be eliminated once we developed the case-mix methodology that would apply for the ESRD PPS bundled payment. The use of this methodology allowed CMS to provide additional payment for the pediatric ESRD population under the composite rate in a data-driven manner to account for the higher costs pediatric patients faced (69 FR 66327).

Section 153(b) of MIPPA added section 1881(b)(14) of the Act, which required CMS to implement an ESRD bundled PPS beginning January 1, 2011, under which a single payment for renal dialysis services is made in lieu of any other payment. Renal dialysis services generally include items and services included in the composite rate for renal dialysis services as of December 31, 2010 and services furnished to individuals for treatment of ESRD, which were formerly separately billable, including drugs and biological products and laboratory tests. In the CY 2011 ESRD PPS proposed rule, we proposed a single composite rate modifier of 1.199 for all Pediatric ESRD Patients receiving dialysis (74 FR 49982 through 49983). A “Pediatric ESRD Patient” is defined as an individual less than 18 years of age who is receiving renal dialysis services. 42 CFR 413.171. We also proposed an eight-group system for separately billable renal dialysis services furnished to Pediatric ESRD Patients with two subdivisions for each of the following factors: age (under 13, 13 to 17), modality (hemodialysis, peritoneal dialysis) and number of comorbidities (none, one or more) (74 FR 49983 through 49987). The CY 2011 ESRD PPS proposed rule then calculated an “expanded bundle” modifier, which combined the composite rate and separately billable modifiers for each of the eight groups (74 FR 44987). These expanded bundle modifiers were the proposed pediatric patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS. These

modifiers were based on a regression of costs for all renal dialysis services furnished to Pediatric ESRD Patients. Comments on this proposed rule indicated that many interested parties felt the expanded bundle modifier was insufficient (75 FR 49128). In the CY 2011 ESRD PPS final rule, we responded to those comments by implementing the first iteration of the current four-group system for both the expanded bundle and the separately billable services. This methodology was data driven, but unlike the simple regression for composite rate costs, allowed for different Medicare payment amounts based on two sets of two characteristics: age of the patient (under 13 or 13 to 17) and modality of the treatment (hemodialysis or peritoneal dialysis). Additionally, this methodology used the same groups for the expanded bundle and separately billable modifiers (75 FR 49134).

We codified the Pediatric ESRD Patient payment adjustment in § 413.235(b), which states that CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality. These multipliers were updated in the CY 2016 ESRD PPS final rule using the same methodology (80 FR 69001 through 69002). The current expanded bundle case mix adjusters are presented below in Table 7.

TABLE 7: Current Pediatric ESRDB Payment Modifiers

Current Pediatric ESRD Expanded Bundle Payment Modifiers by Age and Modality (effective 1/1/2016)		
Age	<13	13-17
Hemodialysis	1.306	1.327
Peritoneal Dialysis	1.063	1.102

Despite these changes intended to improve payment accuracy for renal dialysis services furnished to Pediatric ESRD Patients, we continue to receive comments and concerns from interested parties that the payment amounts for renal dialysis services furnished to Pediatric ESRD Patients are too low. In addition to comments received through the annual ESRD PPS rulemaking, we have also solicited comments from interested parties on several occasions. During the December 2020 TEP, we queried a panel of experts on how to improve payment for

pediatric dialysis care under the ESRD PPS. Panelists¹⁸ generally preferred creating more refined case-mix adjusters over creating an entirely new pediatric ESRD PPS, citing the costs of creating an entirely new system both on CMS and the ESRD facilities and the need for new legislation to be able to increase payment through a separate pediatric ESRD PPS. Panelists also pointed to labor costs as a major reason for higher costs among pediatric dialysis clinics, because these patients need more nursing attention and specialized pediatric nutritionists.

In the CY 2023 ESRD PPS proposed rule (87 FR 38529), we issued a request for information regarding health equity for pediatric patients with ESRD. Many commenters asserted that Medicare payments for Pediatric ESRD Patients are too low and that the ESRD PPS bundled payment does not target the unique issues facing ESRD facilities furnishing renal dialysis services to Pediatric ESRD Patients.

We are committed to improving health equity for Pediatric ESRD Patients receiving renal dialysis services by improving payment equity through more efficient Medicare payments. Ensuring Medicare payments are appropriate and reflect costs for renal dialysis services furnished to Pediatric ESRD Patients would allow more ESRD facilities to provide quality care to this vulnerable population. The main barrier to payment equity is the lack of sufficient data to determine the relative costs associated with furnishing renal dialysis services to Pediatric ESRD Patients. To improve payment rate accuracy for Pediatric ESRD Patients, CMS has issued changes to the cost reports for both freestanding ESRD facilities and hospital-based ESRD facilities effective January 1, 2023.^{19,20,21} These changes include separate categories for labor and supplies used in furnishing renal dialysis services to Pediatric ESRD Patients. These updates are intended to provide data for CMS to more comprehensively estimate the additional costs associated with furnishing renal dialysis services to Pediatric ESRD Patients. However, we

¹⁸ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

¹⁹ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r7p242>.

²⁰ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i>.

²¹ 87 FR 26760 (May 5, 2022). <https://www.federalregister.gov/documents/2022/05/05/2022-09581/agency-information-collection-activities-submission-for-omb-review-comment-request>.

estimate it would take approximately 3 years to obtain and analyze the granular data provided by the stratified cost reports data from these changes that we need in order to consider proposing a more finely-tuned payment adjustment.

(2) Proposed Alternative Methodology for Estimating Relative Costs for Furnishing Renal Dialysis Services to Pediatric ESRD Patients

As noted previously, payment accuracy has been historically difficult for pediatric ESRD dialysis because of the small sample size of Pediatric ESRD Patients receiving renal dialysis services paid for under the ESRD PPS. Pediatric ESRD dialysis treatments are also furnished differently from adult ESRD dialysis treatments in several crucial ways. For example, pediatric ESRD facilities are more likely to be hospital-based and, on average, have lower treatment volume and are located in higher wage index areas. These systematic differences in treatment, when combined with the small sample size, make it very difficult to obtain low variance estimates of the differences in costs between pediatric and adult ESRD dialysis patients. Even if simple cost models show statistically significant estimates, it is possible that the systematic differences between pediatric and adult ESRD facilities can bias these estimates. Obtaining a reliable estimate of the additional costs that Pediatric ESRD Patients incur would allow us to create a payment adjustment to bring relative Medicare payments more in line with relative costs.

One can account for this bias by selecting a specific sample of ESRD facilities that have similar characteristics except for proportion of dialysis treatments furnished to Pediatric ESRD Patients. This would help to show the additional costs of furnishing dialysis to Pediatric ESRD Patients based on the variation in costs across the ESRD facilities. To achieve this, we would use propensity score matching (PSM).

PSM is a technique that uses regression analysis to account for systematic differences between two populations to isolate the effects of a single variable, in this case percentage of Pediatric ESRD Patients. The PSM regression includes a wide range of ESRD facility-level

characteristics including facility type, size, geographic location, and the pediatric ESRD dialysis population nearby the ESRD facility in order to make a propensity score. This propensity score represents the probability that a given ESRD facility treats a high volume of Pediatric ESRD Patients given its facility-level characteristics.

Once the propensity score for each ESRD facility is determined, each ESRD facility with a significant percentage of Pediatric ESRD Patients (high-pediatric) is matched with the ESRD facility without a significant percentage of Pediatric ESRD Patients (low-pediatric) with the most similar propensity score. We can then compare the relative per-treatment costs of those ESRD facilities to estimate the additional costs an ESRD facility faces when it furnishes renal dialysis services to a higher proportion of Pediatric ESRD Patients, controlling for some important facility-level characteristics. The dependent variable of this regression is the log of the cost per treatment for the ESRD facility. The independent variables are the percent of dialysis treatments that are furnished to Pediatric ESRD Patients, the log of the facility size, the type of ESRD facility (hospital based, children's hospital based or freestanding), the log of the wage index for the ESRD facility and the year for the cost report data. The regression equation for cost per treatment given a certain percentage of dialysis treatments furnished to Pediatric ESRD Patients is:

$$\text{Log}\left(\frac{\text{Cost}}{\text{Treatment}}\right) = \text{Pediatric Share} + \log(\text{Facility Size}) + \text{Hospital Type} + \log(\text{wage Index}) + \text{Year Indicator}$$

This cost regression should be unbiased due to the use of PSM. However, PSM also requires a reduction in sample size, because there are relatively few ESRD facilities with a significant number of treatments furnished to Pediatric ESRD Patients that could be matched using PSM. This smaller sample size inherently results in an increase in margin of error. We believe this is a necessary tradeoff because a biased estimate cannot be relied upon, but we must be cautious while using high-error estimates. The final result of this regression is that ESRD facilities that solely serve Pediatric ESRD Patients incur costs that are 40 percent higher per patient for furnishing renal dialysis services than similar ESRD facilities that serve no Pediatric

ESRD Patients. The confidence interval of this estimate is 20 percent to 60 percent. Therefore, on average, furnishing renal dialysis services to a Pediatric ESRD Patient costs 40 percent more than furnishing renal dialysis services to an adult patient with ESRD.

(3) Current Medicare Payments for Renal Dialysis Services Furnished to Pediatric ESRD Patients

The ESRD PPS already accounts for some of the higher costs that ESRD facilities incur while furnishing renal dialysis services to Pediatric ESRD Patients through the case-mix adjusters. Because the analysis described above uses cost report data, it does not incorporate either the current case-mix adjusters or payment rates for Pediatric ESRD Patients receiving renal dialysis services. Our most recent estimates show that payments for dialysis treatments furnished to Pediatric ESRD Patients were approximately 10 percent higher than for adult patients with ESRD in CY 2022.

We are striving for payment accuracy, which is achieved when relative Medicare payments are proportional to relative costs. There are several ways we could adjust ESRD PPS payments to achieve payment accuracy, including calculating the unaccounted-for cost differential, which is the amount by which ESRD PPS payments for pediatric ESRD renal dialysis services must be increased to achieve payment accuracy. We could do this by reducing the cost differential estimate of 40 percent by a factor 1.1 to account for the current payment differential of 10 percent. This would yield an unaccounted-for cost differential of approximately 30 percent ($1.4 \div 1.1 = 1.27$ which we are rounding to 1.3). This is a reasonable estimate of the additional labor and supply costs, which are not accounted for by the current case-mix adjusters, incurred by ESRD facilities furnishing renal dialysis services to Pediatric ESRD Patients.

(4) Proposed Transitional Pediatric ESRD Add-on Payment Adjustment

Despite the high margin of error of the cost regression using PSM, we believe that 30 percent cost is the most reasonable estimate of the unaccounted-for costs incurred in treating

Pediatric ESRD Patients compared to adult ESRD patients. Creating a new add-on payment adjustment using this figure would provide pediatric ESRD facilities with Medicare payments proportional to their estimated costs for a temporary period while we collect additional data. However, due to the high margin of error of the model, increasing Medicare payments to ESRD facilities such that payments are 40 percent higher for Pediatric ESRD Patients compared to all patients would risk making payments higher than appropriate. When we conduct the analysis with the more comprehensive cost report data provided by the cost report changes implemented for CY 2023, we might find that our analysis overestimated the cost of furnishing renal dialysis services to Pediatric ESRD Patients (that is, that the additional 30 percent payment adjustment was too large). If we finalize this transitional add-on payment adjustment for Pediatric ESRD Patients as proposed, pediatric ESRD facilities should be prepared for the possibility that the payment rate for Pediatric ESRD Patients could decrease in the future, should that be indicated by future data analysis and finalized through notice-and-comment rulemaking. One alternative would be for CMS to propose a smaller, more cautious add-on payment adjustment based on the 20 percent lower bound of the confidence interval, leading to an additional 10 percent transitional add-on payment adjustment after accounting for the current payment rate. This option would still represent a significant increase in Medicare payments to ESRD facilities for Pediatric ESRD Patients without much risk of making payments higher than appropriate. However, this alternative option may lead to underpayment to ESRD facilities serving Pediatric ESRD Patients, which is contrary to our goal of aligning resource use with payment. We are seeking comment on the most appropriate amount for the proposed transitional add-on payment adjustment.

We are proposing a new transitional add-on payment adjustment of 30 percent (adjustment factor of 1.3) for dialysis treatments furnished to Pediatric ESRD Patients for 3 calendar years, effective January 1, 2024. Based on the time lag for cost report data, 3 years should allow for enough time for CMS to get more detailed data from the changes to the cost

reports described above. After that period, we would evaluate the more comprehensive cost report data from the first year of cost reporting periods beginning on or after January 1, 2023, to refine our methodology for determining the payment rate for pediatric ESRD dialysis. As proposed, this would be a separate, additional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230, which reflects the other patient and facility level adjustments. This adjustment would not be part of the case-mix adjusters. This payment adjustment would only apply to the ESRD bundled payment and not to any outlier adjustments. Due to the multiplicative nature of the case-mix adjusters it would function similarly to a 30 percent increase to the expanded bundle case-mix adjusters. For the purpose of comparison, the effective case-mix adjusters are presented below in Table 8.

TABLE 8: Pediatric ESRDB Effective Payment Modifiers

Pediatric ESRDB Effective Payment Modifiers by Age and Modality				
Age	Modality	Current Case- Mix Adjuster (Effective 1/1/2016)	Proposed 30% Increase Effective Case- Mix Adjusters	Alternative Proposed 10% Increase Effective Case- Mix Adjusters
<13	PD	1.063	1.382	1.169
<13	HD	1.306	1.698	1.437
13-17	PD	1.102	1.433	1.212
13-17	HD	1.327	1.725	1.460

The exact magnitude of the increase in payment would vary based on the age of the patient and the wage index of a given area; we estimate approximately \$80 for (hemodialysis-equivalent) peritoneal dialysis treatments and \$100 for hemodialysis treatments. This would represent a substantial increase in payment for renal dialysis services furnished to Pediatric ESRD Patients, and would account for the extra costs that this population incurs temporarily until additional cost data is available. This payment adjustment would apply for all dialysis treatments furnished to ESRD patients under the age of 18, not solely treatments furnished in pediatric ESRD facilities. This is warranted because many of the additional costs related to the treatment of Pediatric ESRD Patients are not specific to treatments furnished in pediatric ESRD facilities.

We are proposing to call this the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) and make this adjustment budget neutral. In general, add-on payment adjustments under section 1881(b)(14)(D)(iv) of the Act are not statutorily required to be budget neutral under the ESRD PPS, but we believe in this instance that budget neutrality is appropriate, due to the manner in which this adjustment is derived. Other non-budget neutral add-on payment adjustments that we have established under this authority generally account for costs that were not used for the construction of the ESRD PPS bundled payment, such as the TDAPA for calcimimetics (80 FR 69013 through 69027). We have also established certain non-budget neutral add-on payment adjustments for items or services that were not commonplace, and therefore not adequately represented in cost reports, such as home dialysis training (75 FR 49063). However, we have implemented other payment adjustments under this authority in a budget neutral manner; for example, the changes to the wage index in the CY 2023 ESRD PPS final rule were implemented in a budget neutral manner as they represented a shifting of cost allocations, rather than new costs not originally included in the ESRD PPS bundled payment (87 FR 67157). This proposed TPEAPA is primarily for costs that would have been included in the cost reports used in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule. As explained above, the methodology used both in that analysis, and when updating the case-mix adjusters, attributed pediatric ESRD renal dialysis services costs to the general population. Therefore, we believe it would be appropriate to reduce the ESRD PPS base rate to account for the new allocation of costs. Furthermore, any changes to the case-mix adjustments are required by section 1881(b)(14)(A)(ii) of the Act to be budget neutral, which means that any future modifications to the pediatric case-mix adjusters would be budget neutral. The budget neutrality adjustment factor for this proposed TPEAPA consisting of 30 percent of the per treatment payment amount would be 0.999532. Applying this budget neutrality factor to the ESRD PPS base rate would reduce the ESRD PPS base rate by an estimated \$0.12. Under the alternative proposed 10 percent TPEAPA discussed previously in

this section of the proposed rule, the budget neutrality factor adjustment would be 0.999847.

Applying this budget neutrality factor to the ESRD PPS base rate would reduce the ESRD PPS base rate by an estimated \$0.04.

To establish this new TPEAPA, we are proposing to amend § 413.235 by splitting current paragraph (b) into paragraphs (b)(1) and (2). Paragraph (b)(1) would set forth the established age and modality of treatment case mix adjustment methodology as currently stated in paragraph (b). Paragraph (b)(2) would state that beginning January 1, 2024, we would provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during calendar years 2024, 2025, and 2026. We are also proposing to revise the current language of § 413.235(b) to use the term “Pediatric ESRD Patients,” which is defined at § 413.171, to improve clarity for this section.

(5) Costs and benefits for a proposed Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA)

We believe that CMS could better align the resource use of pediatric ESRD renal dialysis services with payment. Our analysis using the methodology outlined above has found that Pediatric ESRD Patients receiving renal dialysis services have an estimated 40 percent higher costs than adult patients and that the current payment adjusters account for 10 percent higher costs. Implementing a transitional 30 percent add-on payment adjustment for renal dialysis services furnished to Pediatric ESRD Patients would improve payment equity for these patients by increasing payments to more closely align with the estimated costs of treatment. A 30 percent increase in ESRD PPS payments for pediatric ESRD renal dialysis services would represent approximately \$80 to \$100 per pediatric ESRD dialysis treatment, although the exact magnitude of the increase would depend on age, modality and the wage index of the area. This payment increase would have beneficial health equity impacts on this population by improving access to care and quality of care. Some ESRD facilities may not be able to absorb the additional expense

of the Pediatric ESRD Patient population. Patients may need to travel to a limited number of primarily hospital-based ESRD facilities where pediatric ESRD dialysis is performed. As a result, this population may be underserved and disadvantaged with respect to access to ESRD care. Additional payment to those ESRD facilities treating Pediatric ESRD Patients would thereby benefit this potentially underserved and disadvantaged population of Pediatric ESRD patients. Additionally, this would have a beneficial financial impact on the ESRD facilities, both pediatric and non-pediatric, that serve this pediatric population.

We are proposing that this payment adjustment be budget neutral, which would lead to an estimated decrease of \$0.12 to the ESRD PPS base rate, corresponding to a budget neutrality factor of 0.99954. This relatively small adjustment would represent less than a twentieth of a percent of the total ESRD PPS base rate. However, we recognize that any decrease in the base rate would represent a monetary loss to ESRD facilities. As stated above, our analysis indicates that this proposed transfer would be reasonable given the likelihood that the methodology used in the case-mix adjusters attributed some pediatric costs to the general population. However, should future analysis of the stratified pediatric cost data indicate that pediatric ESRD renal dialysis services costs are less than 40 percent higher than adult costs, this proposed budget neutral decrease (if finalized as proposed) would mean that the treatments for adult patients with ESRD were slightly underpaid during this proposed 3-year period. In either case there would be a risk of underpayment for one group of patients. We believe that using the mean estimate of the analysis would provide us with the best approach for achieving payment accuracy while we collect additional data. Additionally, the health equity implications of potentially underpaying for Pediatric ESRD Patients receiving dialysis by 20 percent would be significantly higher than the implications of potentially underpaying for adult patients by a less than 0.1 percent. In CY 2021 there were 116 ESRD facilities that furnished more than 2 percent of their dialysis treatments to Pediatric ESRD Patients, out of 7882 total ESRD facilities. These ESRD facilities are a relatively small group, but they are critical for the care of Pediatric ESRD Patients. For

these reasons, we believe that the expected benefits for the proposed TPEAPA would outweigh the costs.

(6) Request for Comments on this Proposal

We believe that providing this proposed 30 percent TPEAPA for calendar years 2024, 2025, and 2026 would be the best approach for improving payment accuracy until more precise data is available. However, we acknowledge that in any case there is a risk of making payments which are higher or lower than appropriate. We are seeking comment on this proposal for an additional 30 percent payment adjustment for renal dialysis services furnished to Pediatric ESRD Patients for 3 calendar years, effective January 1, 2024, and on any alternative add-on payment adjustment amounts, including the 10 percent payment adjustment discussed earlier in this section of the proposed rule.

h. Proposed Reporting Policy for Unused and Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS

(1) Background

As discussed in the CY 2023 PFS final rule (87 FR 69710), many drugs and biological products that are payable under Medicare Part B are dosed in a variable manner such that the entire amount identified on the vial or package is not administered to the patient. For example, many drugs are dosed based on the patient's body weight or body surface area (BSA). Often, these drugs are available only in single-dose containers. As stated in U.S. Food and Drug Administration (FDA) guidance for industry,²² a single-dose container is designed for use with a single patient as a single injection or infusion. The labeling for a drug packaged in a single-dose container typically includes statements instructing users to discard unused portions. When the labeling instructs a health care provider to discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container or other single-use package of a drug after administering a dose to a Medicare beneficiary, the program provides payment for the unused

²² <https://www.fda.gov/media/117883/download>.

and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier (drug amount discarded/not administered to any patient) is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used to report the amount of a drug that is discarded and eligible for payment.

Beginning on January 1, 2017, CMS revised the Medicare Part B JW modifier policy to require the uniform use of the modifier for all claims for separately payable drugs with discarded drug amounts from single-dose containers or single-use packages payable under Part B, in order to more effectively identify and monitor billing and payment for discarded amounts of drugs.^{23,24} The policy does not apply to drugs that are not separately payable, such as packaged hospital outpatient prospective payment system (OPPS) drugs or those administered in federally qualified health centers (FQHCs) or rural health clinics (RHCs).

In the CY 2023 PFS final rule (87 FR 69718 through 69719), we codified our existing policy as discussed in the prior paragraph in Chapter 17 of the Medicare Claims Processing Manual, and required that billing providers report the JW modifier for all separately payable drugs with discarded drug amounts from single-dose containers or single-use packages payable under Part B, beginning January 1, 2023. These changes were promulgated in connection with the implementation of the discarded drug refund program under section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021). In that same CY 2023 PFS final rule (87 FR 69722), we responded to commenters who requested we exempt drugs paid for under the ESRD PPS bundled payment from the discarded drug refund policy. One commenter expressed concern regarding how implementation of the discarded drug refund might inadvertently impact ESRD products, including those used by home dialysis patients (for example, Extraneal, a peritoneal dialysis solution). In response to those comments, we clarified

²³ CR6603: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3538CP.pdf>.

²⁴ MLN Matters® Number MM9603: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf>.

that units for drugs that are packaged under the Medicare ESRD PPS were not subject to the JW modifier policy or the discarded drug refund.

In the same CY 2023 PFS final rule, CMS also finalized a proposal to require billing providers to report the JZ modifier for all such drugs with no discarded drug amounts, beginning no later than July 1, 2023. Specifically, as discussed in the CY 2023 PFS proposed rule (87 FR 46058), we proposed to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts. We stated that to align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single-dose containers or single-use packages payable under Part B for which the JW modifier would be required if there were discarded amounts. Table 9 below provides additional information about these modifiers.

TABLE 9 – JW and JZ Short and Long Descriptors

MODIFIER	SHORT DESCRIPTOR (28-character limit)	LONG DESCRIPTOR
JW	Discarded drug not administered	Drug amount discarded/not administered to any patient
JZ	Zero drug wasted	Zero drug amount discarded/not administered to any patient

We explained that on all claims for single-dose containers or single-use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We noted that we believed the JZ modifier requirement would not increase burden on the provider, because under the current JW modifier policy, the provider already needs to determine whether or not there are any discarded units from a single-dose container or single-use package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. We finalized the JZ modifier requirement in the CY 2023 PFS final rule. Lastly, we noted in the CY 2023 PFS final rule that we would begin claims edits for both the JW and JZ modifier beginning

October 1, 2023 (87 FR 69179). Additional details can be found in Chapter 17 of the Medicare Claims Processing Manual and the JW/JZ modifier frequently asked questions (FAQ) document.²⁵

(2) Current Reporting of the JW Modifier under the ESRD PPS

As discussed in the previous section, the Medicare Part B JW modifier policy generally does not apply to drugs that are not separately payable. The ESRD PPS statute generally requires a single bundled payment for renal dialysis services. Specifically, section 1881(b)(14)(A)(i) requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The only exception is for oral-only drugs, as defined at § 413.234(a), which are currently paid separately under Medicare Part D. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. We note that although the ESRD PPS includes certain add-on payment adjustments such as the TDAPA and TPNIES, these are adjustments to the ESRD PPS base rate and therefore part of the single payment made under the ESRD PPS; these payment adjustments are not separate payments. For example, as described in our TDAPA implementation guidance issued August 4, 2017, and updated January 10, 2018, available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf>, the methodology used to calculate the per treatment payment amount incorporates the cost of the drugs that are paid for using the TDAPA.

Although renal dialysis drugs and biological products paid for under the ESRD PPS are not considered “separately billable” and are not subject to the general Part B JW modifier policy

²⁵ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>.

discussed in the prior paragraph, CMS has previously issued guidance on the use of the JW modifier on ESRD PPS claims for certain circumstances. Chapter 8, section 60.4.5.1 of the Medicare Claims Processing Manual pertains to self-administered supplies of ESAs.²⁶ Under current guidance, when billing for discarded amounts of drugs in accordance with the policy in chapter 17 of this manual, section 40.1, the provider must bill for discarded amounts on a separate line item with the modifier JW. The line item date of service should be the date of the last covered administration according to the plan of care or, if the patient dies, use the date of death. More specifically, in Chapter 17, section 40.1 of the Medicare Claims Processing Manual,²⁷ we state that multi-use vials are not subject to payment for discarded amounts of drug or biological products, with the exception of self-administered ESAs by Method I home dialysis patients, for whom an ESRD facility furnishes and bills for renal dialysis services.²⁸ Current guidance in Chapter 17, section 40.1 of the Medicare Claims Processing Manual states that the ESRD facility must bill the program using the JW modifier for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. We note that separate payment is not made for ESAs under the ESRD PPS; however, ESAs are eligible for outlier payments when the criteria in § 413.237 are met.

Most recently, the March 15, 2022 Change Request²⁹ that established the TDAPA for Korsuva™ (difelikefalin), instructs facilities to use the JW modifier to report the amount of difelikefalin that is discarded and eligible for payment under the ESRD PPS. We note that based

²⁶ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf>.

²⁷ <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf>.

²⁸ Prior to the ESRD PPS, a Medicare ESRD beneficiary could elect to obtain home dialysis equipment and supplies from a supplier that was not a Medicare approved dialysis facility. This was referred to as Method II home dialysis. In the CY 2011 ESRD PPS final rule (75 FR 49061), we stated that all costs associated with home dialysis services (both Method I and Method II) are included in the composite portion of the two equation model, and we stated that effective January 1, 2011, all home ESRD patients would be considered Method I home patients and all Medicare payments for home dialysis services would be made to the ESRD facility.

²⁹ <https://www.cms.gov/files/document/r11295CP.pdf>.

on the latest available data, nearly 40 percent of the TDAPA expenditures for those drugs that were reported in 2022 represented discarded amounts reported using the JW modifier. This represents approximately \$1.3 million in TDAPA expenditures for discarded amounts of difelikefalin. Overall, our analysis of Medicare claims data from 2017 to 2021 finds that approximately 2 percent of ESRD PPS claims indicate discarded or unused portions of drugs or biological products through use of the JW modifier. From 2017 to 2021, we estimate that the total amount of unused product billed from 2017 to 2021 and paid for under the ESRD PPS is approximately \$22 million.

Under our current policy, we do not reduce the single payment under the ESRD PPS for any discarded amounts of renal dialysis drugs or biological products that are reported with the JW modifier. Furthermore, when calculating any adjustments to the ESRD PPS base rate for the TDAPA or outlier payments, we include all units of renal dialysis drugs and biological products billed on the claim for which an adjustment is made, including any discarded amounts of such drugs and biological products. Additionally, we have previously established in the CY 2012 ESRD PPS final rule (76 FR 70243 through 70244) that ESRD facilities may only report units and charges for drugs and biological products actually purchased and may not bill for overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling. Additionally, we explained that consistent with prior rulemaking, under our authority in section 1881(b)(14)(D)(ii) of the Act, we were adopting the average sales price (ASP) policy on overfill for purposes of calculating the outlier payment. That is, we adopted a policy to exclude overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling from consideration for the purposes of calculating outlier payments. We stated we believe the use of the ASP policy for purposes of calculating the outlier payment is appropriate because we believe overfill does not represent a cost to the ESRD facility; thus, overfill should not factor into our determination of outlier payments.

In summary, our longstanding policy for payment under the ESRD PPS, including the calculation of the TDAPA and outlier payment adjustments, includes payment for units of renal dialysis drugs and biological products billed with the JW modifier, but does not allow payment for overfill units. That is, the current ESRD PPS payment policy is consistent with the broader Medicare Part B policy to pay for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling.

(3) Proposed ESRD PPS Policy for Reporting of Discarded Amounts of Renal Dialysis Drugs and Biological Products

As discussed in section II.B.1.j of this proposed rule, we are undertaking analysis of ESRD PPS claims and cost report data in order to better understand the patient-specific costs associated with furnishing renal dialysis services to Medicare beneficiaries. We believe that in order to most appropriately consider potential refinements to the ESRD PPS case-mix adjustments in the future, it is important to understand and have consistent data about the costs associated with the quantities of the renal dialysis drugs and biological products that are actually used by ESRD beneficiaries. This is consistent with our longstanding policy principles, which are reflected by our policy for billing for unused amounts of renal dialysis drugs and biological products under the ESRD PPS. In the CY 2016 ESRD PPS final rule (80 FR 69033), we discussed our existing policy since the inception of the ESRD PPS that all renal dialysis service drugs and biological products prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities, and the units reported on the monthly claim must reflect the amount expected to be taken during that month. We stated that ESRD facilities should use the best information they have in determining the amount expected to be taken in a given month, including fill information from the pharmacy and the patient's plan of care. We noted that any billing system changes to effectuate this change needed to be made as soon as possible, as this requirement had been in effect since the ESRD PPS began in 2011. This

policy is also discussed in the Medicare Benefits Policy Manual, Pub. 100–02, Chapter 11, section 20.3.C.

Consistent with our longstanding billing policies for unused amounts of drugs and biological products and consistent with the requirements for the uniform use of the JW modifier for all claims for separately payable drugs under Part B since 2017, in order to more effectively identify and monitor billing and payment for discarded amounts of drugs, we are proposing to require ESRD facilities to report accurate and consistent data about discarded amounts of single-dose renal dialysis drugs and biological products paid under the ESRD PPS. Further, section 1881(b)(2)(B) of the Act requires the Secretary to prescribe in regulations any methods and procedures to determine the costs incurred by ESRD facilities in furnishing renal dialysis services to beneficiaries with ESRD, and to determine payment amounts for part B services furnished by such ESRD facilities.

Under our longstanding policy, payment is made under the ESRD PPS bundled payment for discarded amounts of renal dialysis drugs and biological products, and such discarded amounts are included in the calculation of the ESRD PPS base rate and any applicable adjustments, such as the TDAPA and the outlier adjustment. Therefore, consistent with the current JW and JZ reporting requirements that were finalized in the CY 2023 PFS final rule for separately payable Part B drugs, we are proposing to require that beginning no later than January 1, 2024, ESRD facilities must report information on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). We are also proposing that ESRD facilities must document any discarded amounts in the beneficiary’s medical record. Additionally, we are proposing to require ESRD facilities to report the JZ modifier for all such renal dialysis drugs and biological products with no discarded amounts, beginning no later than

January 1, 2024. We are proposing to codify these reporting requirements in regulation at § 413.198(b)(5) and (6).

Under this proposal, the amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is administered would be billed on one line (reflected as billing units in the unit field) and any discarded amounts would be billed on a separate line with the JW modifier (reflected as billing units in the unit field). If a renal dialysis drug or biological product from a single-dose container or single-use package is administered and there are no discarded amounts, then we are proposing that a single line would be billed on the claim form with the JZ modifier and the billing units in the unit field. Therefore, on all claims for renal dialysis drugs and biological products from single-dose containers or single-use packages payable under the ESRD PPS, we are proposing that either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We are proposing that claims for renal dialysis drugs and biological products from single-dose containers or single-use packages that do not report either the JW or JZ modifier may be returned as un-processable until claims are properly resubmitted.³⁰ If this proposal is finalized, CMS would publish information about which HCPCS codes would be identified as single-dose containers or single-use package renal dialysis drugs and biological products subject to required reporting of the JW or JZ modifier. We also would plan to issue guidance regarding additional operational considerations and billing instructions specific to the proposed reporting requirements for these products, if finalized.

We are clarifying that, under our proposal, ESRD facilities would not be required to document in the beneficiary's medical record when there are no discarded amounts. Lastly, we

³⁰ Under the basic requirements for all claims at § 424.32(a)(1), a claim must be filed with the appropriate intermediary or carrier on a form prescribed by CMS in accordance with CMS instructions. Chapter 1 of the Medicare Claims Processing Manual, section 70.2.3.1 states that submissions that are found to be incomplete or invalid are returned to the provider (RTP).

are reiterating that, as discussed in the CY 2023 PFS final rule (87 FR 69722), units for renal dialysis drugs and biological products that are bundled under the Medicare ESRD PPS are not subject to the Medicare Part B discarded drug refund program and would continue to be exempted from the Medicare Part B discarded drug refund. We are also clarifying that for any oral-only drugs, as defined in § 413.234(a), to the extent that any such drugs are produced in single-dose containers or single-use packaging, this proposed reporting requirement would not apply until such drugs are paid for under the ESRD PPS.

We believe that this proposed reporting requirement would enable CMS to obtain more reliable information about the extent to which the costs of providing renal dialysis drugs and biological products represent amounts that beneficiaries use as well as amounts that are discarded. We believe this is particularly important because under Medicare Part B, beneficiaries are responsible for paying a 20 percent coinsurance. As noted above, nearly 40 percent of TDAPA expenditures in CY 2022 represented discarded amounts of renal dialysis drugs and biological products. Medicare beneficiaries, therefore, paid approximately \$260,000 in copayments for these discarded amounts. While this currently represents a small amount of payments overall, the cost for discarded renal dialysis drugs and biological products is borne by a very small population of beneficiaries. It is important for CMS to understand the full scope of expenditures, including expenditures that may be incurred by beneficiaries, for discarded amounts of renal dialysis drugs and biological products in the future, which may be more expensive or more widely used than the current drug that is being paid for using the TDAPA under the ESRD PPS. Thus, we are not proposing in this rule to alter payments to ESRD facilities based on the amounts of discarded renal dialysis drugs and biological products reported, but data collected through adoption of the JW and JZ modifier reporting requirements discussed in this section may inform future payment policies, which would be proposed through future notice and comment rulemaking if appropriate.

Based on our analysis of ESRD PPS claims, as well as the billing guidance in sections 8 and 17 of the Medicare Claims Processing Manual, we believe the proposed JW modifier requirement reflects current practices for ESRD facilities, and would not significantly increase burden for ESRD facilities. Additionally, we believe the proposed JZ modifier requirement would not increase burden on ESRD facilities, because under the current guidance provided regarding use of the JW modifier, the ESRD facility should already have processes in place in order to determine, in the case of certain drugs and biological products, whether or not there are any discarded units from a single-dose container or single-use package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. Furthermore, we note that while renal dialysis drugs and biological products that are paid under the ESRD PPS are not considered separately payable, ESRD facilities are permitted to bill and receive separate payment using the AY modifier for drugs and biological products that are not related to the treatment of ESRD. Although we have noted that renal dialysis drugs and biological products paid under the ESRD PPS are not subject to the Medicare Part B drug refund program or the current JW or JZ reporting requirements, any separately payable drugs or biological products that ESRD facilities bill for using the AY modifier would be subject to such policies under Medicare Part B. Therefore, we believe that most ESRD facilities should already be reporting the JW and JZ modifiers in such circumstances, and would reasonably be able to report these modifiers for renal dialysis drugs and biological products as well. We welcome comments on this assumption and on these proposed JW and JZ reporting requirements for the ESRD PPS.

i. Proposed New Add-on Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends

(1) Background on the TDAPA

Section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous (IV) products into the ESRD PPS bundled payment as part of the

CY 2016 ESRD PPS rulemaking. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process based on our longstanding drug designation process that allowed us to include new injectable and intravenous products into the ESRD PPS bundled payment and, when appropriate, modify the ESRD PPS payment amount. We codified this process in our regulations at 42 CFR 413.234. We finalized that the process is dependent upon the ESRD PPS functional categories, consistent with the drug designation process we have followed since the implementation of the ESRD PPS in 2011. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69014), when we implemented the ESRD PPS, drugs and biological products were grouped into functional categories based on their action. This was done to add new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs are commercially available so beneficiaries have access to them. As we stated in the CY 2011 ESRD PPS final rule, we did not specify all the drugs and biological products within these categories, because we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified, and we wanted the ability to reflect new drugs and biological products developed or changes in standards of practice (75 FR 49052).

In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077). We finalized a policy in the CY 2016 ESRD PPS final rule that if a new renal dialysis injectable or IV product falls within an existing functional category, the new injectable drug or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. We noted in that rule that the ESRD bundled market basket update is used to increase the ESRD PPS base rate annually and accounts for price changes of the drugs and biological products. We also finalized in the CY 2016 ESRD PPS final rule that, if the new renal

dialysis injectable or IV product does not fall within an existing functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA codified in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. The new injectable or IV product is not eligible as an outlier service during the TDAPA period. We established that following the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

In the CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, we revised the regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration. In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, rather than just those in new ESRD PPS functional categories. In the CY 2020 ESRD PPS final rule, we revised § 413.234(b) and added paragraph (e) to exclude from TDAPA eligibility generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the “parent NDA” is a Type 3, 5, 7, or 8, effective January 1, 2020.

Under our current TDAPA policy at § 413.234(c), a new renal dialysis drug or biological product that falls within an existing ESRD PPS functional category is considered included in the ESRD PPS base rate and is paid the TDAPA for 2 years. After the TDAPA period, the ESRD PPS base rate will not be modified. If the new renal dialysis drug or biological product does not fall within an existing ESRD PPS functional category, it is not considered included in the ESRD PPS base rate, and it will be paid the TDAPA until sufficient claims data for rate setting analysis is available, but not for less than 2 years. After the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological product in the ESRD PPS bundled payment.

As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a potential pathway toward a potential ESRD PPS base rate modification (83 FR 56935). For the complete history of the TDAPA policy, including the pricing methodology, please see the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CY 2019 ESRD PPS final rule (83 FR 56932 through 56948), and CY 2020 ESRD PPS final rule (84 FR 60653 through 60681).

(2) Request for Information in the CY 2023 ESRD PPS Proposed Rule

In the CY 2023 ESRD PPS proposed rule (87 FR 38522 through 38523), we summarized the concerns of interested parties and issued a request for information about methods that could be used to develop an add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA. We explained that since 2019, dialysis

associations and pharmaceutical representatives have expressed concerns to CMS about payment following the TDAPA period for new renal dialysis drugs and biological products that are paid for using the TDAPA. We noted that these interested parties have asserted that unless money is added to the ESRD PPS base rate for these drugs and biological products, similar to what occurred with calcimimetics (85 FR 71406 through 71410), then it is unlikely that ESRD facilities would be able to sustain the expense of these drugs and biological products when the TDAPA period ends. Further, these interested parties cautioned that uncertainty about payment could affect ESRD facility adoption of these drugs and biological products during the TDAPA period. We noted that to date, calcimimetics are the only renal dialysis drugs or biological products that have been paid for using the TDAPA and incorporated into the ESRD PPS bundled payment following the TDAPA payment period. We stated that there have been no other renal dialysis drugs or biological products that have completed their TDAPA payment period, and as a result, CMS does not yet have data on other drugs or biological products in order to evaluate the specific risks and access challenges that interested parties have raised.

We also discussed that, as mentioned in the CY 2019 (83 FR 56941) and CY 2020 (84 FR 60672 and 60693) ESRD PPS final rules, many commenters have suggested a rate-setting exercise at the end of the TDAPA period for all new renal dialysis drugs and biological products. We responded to those comments by noting that we do not believe adding dollars to the ESRD PPS base rate would be appropriate for new drugs that fall into the ESRD PPS functional categories, given that the purpose of the TDAPA for these drugs is to help ESRD facilities incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provide additional payments for such associated costs, and promote competition among the products within the ESRD PPS functional categories. In addition, we explained that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. We stated that under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the

average patient, and that there would be patients whose treatment costs at an ESRD facility would be more or less than the ESRD PPS payment amount. We noted that a central objective of the ESRD PPS and of prospective payment systems in general is for ESRD facilities to be efficient in their resource use.

We also noted that price changes to the ESRD PPS bundled payment are updated annually by the ESRDB market basket update, which includes a pharmaceutical cost category weight. In addition, we explained that our analysis of renal dialysis drugs and biological products paid for under the ESRD PPS has found costs and utilization to have decreased over time for some high volume formerly separately billable renal dialysis drugs, relative to overall market basket growth. Therefore, we stated that we believe that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.

We noted that section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—(I) for pediatric providers of services and renal dialysis facilities; (II) by a geographic index, such as the index referred to in section 1881(b)(12)(D), as the Secretary determines to be appropriate; and (III) for providers of services or renal dialysis facilities located in rural areas. Regarding the patient access concerns that we discussed in the CY 2023 ESRD PPS proposed rule, we stated that we were considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends. We noted that any add-on payment adjustment would be subject to the Medicare Part B beneficiary co-insurance payment under ESRD PPS.

In the CY 2023 ESRD PPS proposed rule, we presented four potential methods that we were considering, which we noted could be used to develop an add-on payment adjustment for these drugs and biological products. We noted that the methods presented differed in terms of

which formerly separately billable renal dialysis drugs and biological products would be considered for a potential add-on payment adjustment. We further noted that under these potential options, we would apply a reconciliation methodology only when an add-on payment adjustment would align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category. The four options are summarized as follows:

- Reconcile the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products. For example, if the reduction in the cost of all formerly separately billable renal dialysis drugs and biological products per treatment excluding the renal dialysis drug or biological product that was paid for using the TDAPA is \$5 and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is \$10, the add-on payment adjustment per treatment would be \$10 minus \$5, which is \$5. The reductions in formerly separately billable renal dialysis drug and biological products expenditures per treatment would be calculated by using the difference between these expenditures in the most recent year with claims data available and these expenditures in the current base year for the ESRDB market basket, which is CY 2020. We provided the following example: If the rule year for which we are calculating the add-on payment adjustment is CY 2023 and the base year for the ESRDB market basket is CY 2020, the reduction in formerly separately billable renal dialysis drugs and biological products expenditures would be the difference between these expenditures in CY 2021 (the year with the most recent claims data) and those in CY 2020.

- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products, where such reduction can be empirically attributed to the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the utilization of the renal dialysis drug or biological

product that was paid for using the TDAPA was found to be statistically associated with reduction in expenditure of one drug in an ESRD PPS functional category amounting to \$1 per treatment, and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is \$10, the add-on payment adjustment per treatment would be \$10 minus \$1, which is \$9.

- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs that fall into one or more ESRD PPS functional categories, where such expenditure reduction is data-driven, based on end action effect, to be attributable to the renal dialysis drug or biological product that was paid for using the TDAPA. Such a data-driven determination would be made by CMS. For example, if the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is \$10 and the reduction in the expenditure for other clinically related formerly separately billable renal dialysis drugs is \$0.50 per treatment, the add-on payment adjustment would be \$10 minus \$0.50, which is \$9.50.

- Only use the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the per treatment cost of the renal dialysis drug or biological product that was paid for using the TDAPA is \$10, this would be the amount of the add-on payment adjustment.

Following the discussion in the CY 2023 ESRD PPS proposed rule about these potential methodologies, we issued a request for information within that proposed rule (87 FR 38523) to seek feedback from the public on the following questions.

- Is an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends needed? If so, why? What criteria should CMS establish to determine which renal dialysis drugs or

biological products would be included in the calculation for an add-on payment adjustment after the TDAPA period ends?

- If an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period is needed, are the methods discussed in section II.D.4 of the CY 2023 ESRD PPS proposed rule sufficient to address the add-on payment adjustment?

++ Which method would be most appropriate?

++ Are there changes to the methodologies that CMS should consider to improve our ability to align payment for renal dialysis services with resource utilization? Please provide as much detail as possible.

++ Are there other methodologies that CMS should consider? Please provide as much detail as possible.

We noted that while we would not be responding to specific comments submitted in response to this RFI, we intended to use this input to inform future policy development. We stated that any potential payment policies related to this RFI would be proposed through a separate notice and comment rulemaking.

We provided a high-level summary of responses to this RFI in the CY 2023 ESRD PPS final rule (87 FR 67219 through 67220) and noted that we would publish more detailed information about the commenters' recommendations in a future posting on the CMS website located at the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources. We noted that we received 27 public comments regarding our RFI, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large, non-profit health system; and MedPAC.

In the CY 2023 ESRD PPS final rule, we stated that most commenters expressed their belief that an add-on payment adjustment of this nature is necessary to support the adoption of

new renal dialysis drugs and biological products, and that most commenters stated that they supported CMS allowing all new renal dialysis drugs and biological products to be eligible to receive an add-on payment adjustment after the TDAPA period ends. However, we noted that MedPAC opposed this type of add-on payment adjustment by stating that it would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices. We also noted that MedPAC recommended that CMS limit the add-on payment adjustment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products reflected in the ESRD PPS bundled payment.

We further noted in the CY 2023 ESRD PPS final rule that several commenters stated they supported reconciling the expenditure of the new renal dialysis drug or biological product with any reduction in expenditures for other formerly separately billable renal dialysis drugs that are clinically or statistically related to the introduction of the new renal dialysis drug in the bundle. Several commenters expressed their belief that the FDA-approved label should be used to determine the primary indication and clinical association, rather than end-action effect. MedPAC expressed opposition to calculating any add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends, but noted that if an add-on payment adjustment were applied, it would be appropriate to use an offset, similar to the approach used with the TPNIES, to avoid duplicative payment for renal dialysis services already included in the ESRD PPS base rate.

(3) Proposed Add-on Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products after the TDAPA Period Ends

As discussed previously, section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Based on the public comments received regarding the RFI in the CY 2023 ESRD PPS proposed rule,³¹ we believe it is appropriate to propose, beginning January 1, 2024, an add-on payment

³¹ <https://www.cms.gov/files/document/cy-2023-esrd-pps-payment-after-tdapa-rfi-summary-comments.pdf>.

adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We note that this proposed post-TDAPA payment adjustment would not apply to new renal dialysis drug or biological products used to treat or manage a condition for which there is not an ESRD PPS functional category, because we have already established a policy to modify the ESRD PPS base rate for such products, if appropriate, after the TDAPA period ends, to account for the products in the ESRD PPS bundled payment (§ 413.234(c)(2)(i)).

We agree with commenters who expressed concerns that the ESRD PPS' current mechanisms may not fully account for the costs of these new drugs. Several commenters asserted that the outlier adjustment and the market basket updates cannot adequately account for these costs, and several organizations noted that if renal dialysis drugs and biological products with significant costs were adopted under the outlier policy, the threshold to qualify for outlier payments would increase dramatically, thus adversely affecting access to products traditionally eligible for the outlier payment adjustment. Commenters expressed that this increase in the outlier threshold may also raise health equity concerns because, as we noted in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67171), the outlier adjustment protects access for beneficiaries whose care is unusually costly. We recognize that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the TDAPA, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries. Additionally, several commenters raised concerns about the ability of the market basket to account for the cost of new renal dialysis drugs and biological products. These commenters referred to a Moran study³² suggesting that the drug proxies historically used in updating the ESRD PPS base rate have not adequately accounted for the costs of non-ESA drugs under existing functional categories. While we continue to believe that the market basket price

³² Kidney Care Partners. August 4, 2022. Comment Letter. <https://kidneycarepartners.org/wp-content/uploads/2022/08/KCP-PPS-Comment-Letter-Part-1-Final.pdf>. Accessed May 16, 2023.

proxies are the best available information for projecting the future costs of renal dialysis drugs and biological products, and that they provide an adequate mechanism for projecting future ESRD PPS cost growth, we recognize that there is additional uncertainty about future trends in the expenditures for new renal dialysis drugs and biological products, including trends in pricing and utilization of such drugs and any equal substitutes such as generic drugs.³³ We believe these trends could be more effectively analyzed by collecting additional ESRD facility cost data following the 2-year TDAPA period. We recognize that although the TDAPA for drugs and biological products in existing ESRD PPS functional categories enables ESRD facilities to incorporate new renal dialysis drugs and biological products into their businesses, additional support may be needed to assure continued access to such drugs and biological products for Medicare beneficiaries and to support ESRD facilities' long-term planning and budgeting. We also recognize the importance of providing an appropriate pathway for ESRD facilities to incorporate new renal dialysis drugs and biological products into their business operations. In the CY 2019 ESRD PPS final rule in which we first established the 2-year TDAPA period for new renal dialysis drugs and biological products in an existing ESRD PPS functional category (83 FR 56934), we acknowledged that ESRD facilities have unique circumstances with regard to implementing new drugs and biological products into their standards of care. For example, we stated that when new drugs are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate the new therapies in their care plans. We noted that newly launched drugs and biological products can be unpredictable with regard to their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, we stated that practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes. We noted that we agreed this uptake period would be best supported by the TDAPA pathway because it would help ESRD facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. We

³³ <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers>.

continue to believe that the 2-year TDAPA period is appropriate and achieves its stated goals. However, we also recognize that continuity and predictability is an integral part of ESRD facilities' ongoing business operations. We agree with commenters' concerns that a sudden decrease in payments after the end of the TDAPA for these products could result in a decrease in access for these new renal dialysis drugs and biological products. We are therefore proposing to establish a new transitional add-on payment adjustment that would provide an appropriate transition of the level of payment following the TDAPA period for these drugs. For ease of reference, we are proposing to refer to this proposed add-on payment adjustment as the post-TDAPA add-on payment adjustment. Our goals for the post-TDAPA add-on payment adjustment are to ensure that in circumstances when the ESRD PPS base rate is not modified because a new renal dialysis drug or biological product is used to treat or manage a condition for which there is an ESRD PPS functional category and is therefore considered included in the ESRD PPS bundled payment, payment after the TDAPA is not a barrier to Medicare beneficiaries' access to such new products. We also want to support ESRD facilities' long-term planning with respect to continuing to budget and plan for new renal dialysis drugs and biological products that ESRD facilities have incorporated into their businesses during the TDAPA period. In addition, in accordance with the goals of prospective payment under the ESRD PPS, our goal for the post-TDAPA add-on payment adjustment is to incentivize ESRD facilities to be efficient in the use of resources.

We do not agree with MedPAC's statement that a post-TDAPA add-on payment adjustment would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices. As discussed in the following section, we are proposing to apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments following the end of the TDAPA period and would not limit the adjustment to claims that include the new renal dialysis drug or biological product. We believe that this proposed methodology would appropriately align incentives for ESRD facilities and would support competition with existing

drugs, because payment for an individual claim would not be dependent on individual utilization of the new renal dialysis drug or biological product. Thus, we anticipate that the proposed methodology would create incentives for ESRD facilities to efficiently allocate resources in a way that would be consistent with the principles of prospective payment. We note that when Erythropoietin (EPO) switched from being separately payable to being paid for under the ESRD PPS beginning in CY 2011, these incentives to efficiently allocate resources resulted in decreases in expenditures for these drugs while also providing increased payment to ESRD facilities that supported beneficiaries' access to the new renal dialysis drugs and biological products. Because of these incentives, which would encourage ESRD facilities to efficiently allocate resources, we anticipate that the proposed methodology would not encourage higher launch prices for new renal dialysis drugs and biological products, as manufacturers would need to price such drugs and biological products appropriately to compete with existing drugs and biological products included in the ESRD PPS bundled payment.

We also do not agree with MedPAC's recommendation that CMS limit the post-TDAPA add-on payment adjustment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products reflected in the ESRD PPS bundled payment. As stated previously, we recognize that continuity and predictability is integral to ESRD facilities' operations, and we do not believe that this principle applies only to drugs and biological products that show a substantial clinical improvement. As we explained in the CY 2023 ESRD PPS final rule (87 FR 67189), the intent of the ESRD PPS functional category framework is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician. As we further explained in the CY 2023 ESRD PPS final rule, the functional category structure helps to ensure the ESRD patient has broad access to all renal dialysis service drugs, which is a distinct benefit to the patient. In addition, the structure of the functional categories helps to ensure the treating physician has a broad array of drugs to meet the specific, individual needs of each ESRD patient, including differing pharmaceutical

profiles, comorbidities, contra-indications with other drugs the patient may be taking, and personal patient preference (87 FR 67189). We do not believe that limiting the post-TDAPA add-on payment adjustment based on CMS's determination of substantial clinical improvement would align with this stated intent of the ESRD PPS functional category framework to support broad access to all renal dialysis service drugs. We further note that the current TDAPA exclusion criteria under § 413.234(e) consider FDA's determination of the drug's new drug application (NDA) type or approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which is less subjective than a determination of substantial clinical improvement. Furthermore, we believe that our proposed methodology for the post-TDAPA add-on payment adjustment would incentivize ESRD facilities' efficient use of resources, because as previously stated, payment for an individual claim would not be dependent on individual utilization of the new renal dialysis drug or biological product. Accordingly, we believe that under our proposed methodology, for new renal dialysis drugs and biological products that are not a substantial clinical improvement over existing renal dialysis drugs and biological products, utilization would diminish over time and the amount of the post-TDAPA add-on payment adjustment would decline accordingly. As discussed earlier in this proposed rule, we anticipate that the incentives for ESRD facilities under the proposed methodology for the post-TDAPA add-on payment adjustment would result in competition between new and existing renal dialysis drugs and biological products, and that this competition would serve to drive down prices of such new renal dialysis drugs and biological products over time.

We are proposing to calculate the post-TDAPA add-on payment adjustment following the methodology described in the following subsections for any new renal dialysis drug or biological product that is paid for using the TDAPA under § 413.234(c)(1). We are proposing that the post-TDAPA add-on payment adjustment would be applied for a period of 3 years following the end of the TDAPA period for those products. We believe that a 3-year payment period would provide sufficient time for CMS to analyze cost reports that include costs for the new renal

dialysis drug or biological product paid for using the TDAPA under the ESRD PPS, in order to incorporate changes as appropriate to the ESRD PPS market basket price proxies. The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. The proposed 3-year payment period for the post-TDAPA add-on payment adjustment would allow CMS to evaluate how the new drug or biological product affects the overall mix of renal dialysis drugs and biological products in the ESRDB market basket and to determine the appropriate price proxies for such new drug or biological product. We note that for new renal dialysis drugs and biological products that are not considered included in the ESRD PPS base rate, the TDAPA is paid until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years. Similarly, as described earlier in this paragraph, we are proposing a 3-year payment period for the post-TDAPA add-on payment adjustment, which would enable the collection and analysis of sufficient cost report information and would address the concerns that commenters raised about the effectiveness of the ESRD PPS market basket price proxies to account for the costs of new renal dialysis drugs and biological products going forward by allowing CMS to incorporate data showing trends in use over an adequate period of time. Additionally, we believe that a 3-year period for the post-TDAPA add-on payment adjustment would be appropriate and consistent with the transition period that we finalized at the beginning of the ESRD PPS, when ESRD facilities were transitioned from receiving payments under the composite rate payment system to receiving payments under the ESRD PPS (79 FR 49162). We finalized the transition period for CY 2011 through CY 2013 in order to comply with the requirement of section 1881(b)(14)(E)(i) of the Act to provide a 4-year phase-in of the payment amount under the ESRD PPS, where full implementation of the ESRD PPS payment would occur beginning in the fourth year, CY 2014. We are proposing a similar timeline to provide an appropriate transition for new renal dialysis drugs and biological products in existing ESRD PPS functional categories, which are not eligible

for a modification to the ESRD PPS base rate. Based on the experience of ESRD facilities during the 4-year phase-in from CY 2011 to CY 2014, ESRD facilities would be familiar with this timeline for phasing in major changes that impact their long-term planning and budgeting. Lastly, in the interest of transparency, we note that this 3-year period would provide time for analysis of utilization data for public awareness about the potential need for refinements to the ESRD PPS. Therefore, we are proposing to calculate and apply the post-TDAPA add-on payment adjustment for a period of 3 years following the end of the TDAPA period, with no post-TDAPA add-on payment adjustment calculated beginning in the 4th year.

We are proposing that this post-TDAPA add-on payment adjustment would not be budget neutral, as discussed later in this proposed rule. We note that this proposed post-TDAPA add-on payment adjustment, if finalized, would be calculated for *Korsuva*TM, the only renal dialysis drug currently receiving the TDAPA, and that payment of this post-TDAPA add-on payment adjustment, if finalized, would begin April 1, 2024 at the end of the TDAPA period for *Korsuva*TM.

(a) Calculation of the proposed post-TDAPA add-on payment adjustment

As discussed earlier in this section of the proposed rule, we are proposing to establish a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We are proposing to apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments beginning at the end of a new renal dialysis drug or biological product's TDAPA period. Specifically, we are proposing that the post-TDAPA add-on payment adjustment would begin 8 calendar quarters after the beginning of the first calendar quarter in which TDAPA payment is made for the new renal dialysis drug or biological product in an existing ESRD PPS functional category, and would end no later than the 12th calendar quarter after the last calendar quarter in which TDAPA payment is made. As discussed in the following paragraphs, we believe our proposed calculation of the post-TDAPA add-on payment adjustment would be the most appropriate to address the

patient access concerns we discussed in the CY 2023 ESRD PPS proposed rule and in this section of the proposed rule, and the most consistent with the principles of prospective payment. This proposal would apply the patient-level adjustment factors to the post-TDAPA add-on payment adjustment amount paid on each claim, which would ensure that ESRD PPS payment would support access to new renal dialysis drugs and biological products for beneficiaries with conditions that are costlier to treat, in alignment with our goals as stated earlier in this proposed rule. We are proposing to codify the payment of the post-TDAPA add-on payment adjustment as part of the per treatment payment amount at § 413.230(f). We are proposing to codify the methodology for calculating the post-TDAPA add-on payment adjustment at § 413.234(g). We are proposing to make additional changes under § 413.234(b) and (c) to address payment of the post-TDAPA payment adjustment.

In determining the proposed calculation of the proposed post-TDAPA add-on payment adjustment, we considered the comments that we received regarding the RFI in the CY 2023 ESRD PPS proposed rule. Some commenters expressed that new and innovative drugs may only be used by a small percentage of the dialysis population and suggested that an add-on payment adjustment should address patient-specific needs in order to support access.

First, we considered calculating the post-TDAPA add-on payment adjustment as the average cost for patients that used the new renal dialysis drug or biological product that was previously paid for using the TDAPA under the ESRD PPS, and applying the post-TDAPA add-on payment adjustment only to claims that include the new renal dialysis drug or biological product. However, we are concerned that such an approach would not align with the principles of prospective payment under the ESRD PPS. As we noted earlier in this proposed rule, a central objective of the ESRD PPS (and of prospective payment systems in general) is for ESRD facilities to be efficient in their resource use. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and CMS acknowledges there will be patients whose treatment costs at an ESRD facility would be more or less than the ESRD

PPS payment amount. Additionally, we are concerned that such an approach would result in a substantial cost burden for beneficiaries who use the new renal dialysis drug or biological product, because they incur a 20 percent coinsurance under Part B for renal dialysis services. We do not believe this approach would align with our priorities to reduce drug costs for Medicare beneficiaries. In contrast, our proposed methodology would apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments, which would result in a minimal increase in per-treatment coinsurance amounts for all beneficiaries. As discussed later in this section, we are proposing to apply the ESRD PPS patient-level adjustments to the post-TDAPA add-on payment adjustment for each treatment.

Next, we considered applying the post-TDAPA add-on payment adjustment based only on claims from ESRD facilities that used the new renal dialysis drug or biological product during the TDAPA period. However, like the previous option, we believe that limiting application of this add-on payment adjustment to claims from ESRD facilities that include the new renal dialysis drug or biological product would be inconsistent with the principles of prospective payment. As we discussed in the CY 2011 ESRD PPS final rule, there are patients whose medical treatment results in more costly care as well as those with less costly care, and the ESRD PPS bundled base rate reflects Medicare payment for the average ESRD patient (75 FR 49045). Further, we are concerned that limiting the post-TDAPA add-on payment adjustment to claims from ESRD facilities that use the new renal dialysis drug or biological product could result in substantial overestimation of the post-TDAPA add-on payment adjustment, if more ESRD facilities begin using the new renal dialysis drug or biological product. As we discuss later in this proposed rule, we are proposing to apply this post-TDAPA add-on payment adjustment in a non-budget neutral manner. Therefore, we are concerned that an overestimation of the post-TDAPA add-on payment adjustment could result in an inappropriate increase in Medicare expenditures. As we discussed in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56935; 84 FR 60654), for new renal dialysis drugs and biological products that fall into an

existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate the new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. We believe that after the end of the TDAPA period, ESRD facilities will have made appropriate changes in their business models to adopt such products, and therefore any approach to a post-TDAPA add-on payment adjustment should apply equally to all ESRD PPS treatments, in order to apply the appropriate incentive structures for ESRD facilities' utilization of renal dialysis drugs and biological products and to continue to promote competition among the products within the ESRD PPS functional categories, including the new renal dialysis drug or biological product that was previously paid for using the TDAPA under the ESRD PPS. Furthermore, we believe that such an approach would help to support access to new renal dialysis drugs and biological products to the widest scope of beneficiaries. This is in line with CMS's commitment to advance health equity by supporting access to renal dialysis services.

Accordingly, we are proposing to apply the post-TDAPA add-on payment adjustment to each ESRD PPS treatment, and to adjust it for patient characteristics. In other words, the post-TDAPA add-on payment adjustment would be multiplied by the ESRD PPS patient-level adjustments under § 413.235. We believe this approach would appropriately adjust aggregate ESRD PPS payment to account for the new renal dialysis drugs and biological products in a way that is consistent with the principles of prospective payment, and would support beneficiary access to new renal dialysis drugs and biological products by recognizing the additional patient-specific needs associated with the existing ESRD PPS case-mix adjusters. We note that in order to calculate an appropriate post-TDAPA add-on payment adjustment, we would apply a case-mix standardization factor to the post-TDAPA add-on payment adjustment amount as discussed in the following paragraphs.

In addition, we considered the public comments regarding the need to reconcile estimated expenditures for a new renal dialysis drug or biological product with the declines in expenditures for related drugs. As we noted earlier in this proposed rule, commenters expressed support for establishing a methodology that would consider the decline in estimated expenditures for drugs that are clinically or empirically related to the new renal dialysis drug or biological product. Such a methodology would be highly complex and less transparent than other potential options that commenters suggested. Commenters noted various ideas that CMS would need to consider when attempting to establish the offsetting financial effects of drugs and biological products that are either clinically or empirically-related to the new renal dialysis drug or biological product. For example, most commenters suggested that CMS use drugs with the same FDA clinical indication to offset the payment adjustment, in the interest of transparency and objectivity. However, some commenters, including MedPAC, noted that they do not believe that FDA determinations or ESRD PPS functional categories should be the basis of eligibility for the post-TDAPA payment adjustment, as CMS should make these determinations based on the specific needs of the Medicare population. We believe that such considerations based on specific population needs could be less transparent than alternative approaches, especially in situations when there could, in the future, be multiple new renal dialysis drugs or biological products for which we would be calculating multiple offset adjustments. We anticipate that it would be challenging for CMS to determine, within the annual rulemaking timeframes, the extent to which changes in the utilization of existing renal dialysis drugs and biological products are clinically or empirically related to utilization of a new renal dialysis drug or biological product paid for using the TDAPA. We note that the latest available data at the time of this proposed rulemaking includes less than a full year of TDAPA utilization. We anticipate that as additional data are collected, CMS would be able to analyze trends and may be able to retrospectively determine the extent of any substitution effects between new and existing renal dialysis drugs and biological products. Furthermore, the calculation of these offsets could involve multiple overlapping

periods of time, which would further increase complexity and reduce transparency. As an alternative, we considered MedPAC's suggestion to align the methodology closer to that of the ESRD PPS TPNIES, wherein CMS pays a reduced percentage of the estimated incremental cost of a new product as a risk-sharing mechanism with ESRD facilities and to provide a disincentive for significant increases in drug prices. Under the TPNIES, CMS calculates the TPNIES amount as 65 percent of the MAC-determined price for certain new and innovative equipment and supplies (§ 413.236(f)). We believe this approach would have the same general effect of accounting for declines in other drug expenditures, while being significantly less complex and more transparent. In the CY 2020 ESRD PPS final rule that established the 65 percent cost-sharing proportion for TPNIES, we stated that the goal of TPNIES was to support ESRD facility use of new and innovative renal dialysis equipment and supplies (84 FR 60692). In that same CY 2020 ESRD PPS final rule, we further stated in response to comments that we believe that we need to balance this goal with sharing risk for the new product (84 FR 60697). As noted earlier in this proposed rule, one goal of the proposed post-TDAPA add-on payment adjustment is to support continued access to new renal dialysis drugs and biological products and to support ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period. Additionally, as stated earlier in this section of this proposed rule, our goal is also to incentivize efficient use of resources, consistent with the principles of prospective payment under the ESRD PPS. We believe that applying a cost-sharing proportion of 65 percent to the proposed post-TDAPA add-on payment adjustment would effectively achieve these goals, because it would provide a significant level of payment that supports access for beneficiaries and long-term planning for ESRD facilities, while incentivizing ESRD facilities to efficiently allocate resources by sharing a significant portion of the cost with ESRD facilities. Furthermore, this proposed 65 percent cost-sharing factor would serve to further reduce the minimal cost-sharing burden of new renal dialysis drugs and biological products for beneficiaries, under the proposed post-TDAPA add-on payment methodology. Lastly, we note that for home dialysis machines that are

capital-related assets that qualify for the TPNIES, our policy is to apply an offset to account for the amount of such capital-related assets in the ESRD PPS base rate. As we discussed previously, we considered applying an offset to the proposed post-TDAPA add-on payment adjustment; however, we believe that considerations based on specific population needs could be less transparent than applying a simple 65-percent risk-sharing percentage. Additionally, we noted that in the future, there could be multiple new renal dialysis drugs or biological products for which we would be calculating multiple offset adjustments, which would further increase complexity and reduce transparency. We are soliciting comments on whether there are other ways CMS could consider calculating an offset amount for the post-TDAPA payment adjustment. Alternatively, we seek comment on if there are other ways CMS can ensure any growth in post-TDAPA add-on payment adjustment amounts is reasonable, such as not allowing increases to exceed inflation or other relevant metrics.

We are proposing to calculate the post-TDAPA add-on payment adjustment annually, based on the latest available full calendar quarter of average sales price (ASP) data, which would be consistent with the current policy for determining the basis of payment for the TDAPA. Under current policy, finalized in the CY 2020 ESRD PPS final rule (84 FR 60679), we pay the TDAPA based on 100 percent of ASP. If ASP is not available, we base the TDAPA payment adjustment on wholesale acquisition cost (WAC), and if WAC is not available, then we base payment on invoice pricing. As we stated in the CY 2020 ESRD PPS final rule, we continue to believe that after the TDAPA period, calculating the proposed post-TDAPA add-on payment adjustment for new renal dialysis drugs based on ASP, as compared to WAC or invoice pricing, would be the most appropriate choice for the ESRD PPS, and would strike the right balance in supporting ESRD facilities in their uptake of innovative, new renal dialysis drugs and biological products and limiting increases to Medicare expenditures. We propose to address the annual calculation of the post-TDAPA add-on payment adjustment in the annual proposed and final ESRD PPS rules for future years.

As discussed in section II.B.1.k, under current TDAPA policy, if CMS stops receiving ASP during the TDAPA period, then CMS will stop paying the TDAPA after 2 calendar quarters. Similarly, we believe that if drug manufacturers were to stop submitting ASP data for products that are included in the calculation of the proposed post-TDAPA add-on payment adjustment, and we had to revert to basing calculation of the post-TDAPA add-on payment adjustment on WAC or invoice pricing, we would be overpaying for the proposed add-on payment adjustment. Therefore, we are proposing to make payment of the post-TDAPA add-on payment adjustment conditional on receiving ASP data. Because the post-TDAPA add-on payment adjustment would be calculated annually rather than quarterly, we are proposing that if CMS does not receive the latest full calendar quarter of ASP data for a drug that would be included in the calculation of the post-TDAPA add-on payment adjustment, then CMS would not include that drug in the calculation of the post-TDAPA add-on payment adjustment for any future years. We are also proposing that if CMS stops paying the TDAPA for a drug or biological product because CMS stops receiving the latest full calendar quarter of ASP data, then we would not include that drug or biological product in the calculation of the post-TDAPA add-on payment adjustment for the next CY or any future CY. Consistent with our policy for calculating the TDAPA, as discussed in section II.B.1.k of this proposed rule, we are proposing that in situations when a manufacturer reports zero or negative sales, we would consider CMS to have received the latest full calendar quarter of ASP data, but we would calculate the post-TDAPA payment adjustment based on WAC, or if WAC is not available, on invoice pricing, in such circumstances.

Finally, we are proposing that for each of the 3 years for which this proposed post-TDAPA add-on payment adjustment would be paid, we would update the amount of the post-TDAPA add-on payment adjustment by the ESRD PPS market basket update to account for estimated future input price changes faced by ESRD facilities. We are soliciting comment on whether it would be more appropriate to consider using the growth in the market basket price

proxy for the Pharmaceuticals cost category in the ESRDB market basket, rather than the market basket update.

Therefore, we are proposing to use the following calculation to determine the amount of the post-TDAPA add-on payment adjustment to be applied to each ESRD PPS treatment.

- Step 1, using the most recent available 12 months of claims data, calculate the total expenditure of the new renal dialysis drug or biological product being paid for using the TDAPA under the ESRD PPS. Total expenditure would be calculated by multiplying the latest available full calendar quarter of ASP data for the new renal dialysis drug or biological product by the quantity of units billed. If CMS does not receive the latest available calendar quarter of ASP data for a drug or biological product, then CMS would not apply the post-TDAPA add-on payment adjustment for that drug or biological product. As we noted earlier, if the latest available full calendar quarter of ASP data reflects zero or negative sales, CMS would calculate the post-TDAPA add-on payment adjustment based on WAC, or if WAC is not available, invoice pricing.

- Step 2, divide the total expenditure of the new renal dialysis drug or biological product from Step 1 by the total number of ESRD PPS treatments furnished during the same 12-month period as used in Step 1. The resulting quotient from Step 2 would be the post-TDAPA add-on payment adjustment amount for each treatment, before applying the reduction factor to account for case-mix standardization, as described in Step 4.

- Step 3, calculate the dollar amount of the total aggregate case-mix adjusted post-TDAPA add-on payment adjustment amount by multiplying the post-TDAPA add-on payment adjustment amount from Step 2 by the applicable patient-level adjustments for each ESRD PPS treatment furnished during the 12-month period.

- Step 4, divide the aggregate case-mix adjusted add-on payment adjustment amount from Step 3 by total expenditure from Step 1. The resulting quotient would be the reduction

factor applied to the post-TDAPA add-on payment adjustment amount to account for case-mix standardization.

- Step 5, apply the reduction factor from Step 4 to the post-TDAPA add-on payment adjustment amount from Step 2.
- Step 6, apply the 65 percent risk-sharing factor to the amount from Step 5 to calculate the case-mix adjusted post-TDAPA add-on payment adjustment amount.
- Step 7, multiply the case-mix adjusted post-TDAPA add-on payment adjustment amount by the ESRD PPS market basket update percentage.

We propose to amend 42 CFR 413.234 by revising § 413.234(c)(1)(i) and adding regulations at § 413.234(b)(1)(iii), (c)(1)(ii), (c)(3), and (g) that would describe the post-TDAPA payment adjustment and the calculation we would use to determine the post-TDAPA payment adjustment amount, as described above. In addition, we propose to amend § 413.230 by adding reference to the proposed post-TDAPA add-on payment adjustment in the calculation of the ESRD PPS per treatment payment amount.

In the section below, we provide an example of the proposed calculation for CY 2024 for *Korsuva*TM based on the latest available information at the time of this proposed rulemaking.

We are proposing to follow these steps to calculate the case-mix adjusted post-TDAPA add-on payment adjustment amount for CY 2024 and future years, when appropriate. We are proposing to include in the calculation of the case-mix adjusted post-TDAPA add-on payment adjustment amount any new renal dialysis drugs and biological products in existing ESRD PPS functional categories that are eligible for payment using the TDAPA described in § 413.234(c). We are proposing to begin making payment under this new post-TDAPA add-on payment adjustment 8-calendar quarters after the beginning of the TDAPA payment period for the new renal dialysis drug or biological product. We are proposing that payment of the post-TDAPA add-on payment adjustment would end no later than 12 calendar quarters after the end of the TDAPA payment period for the new renal dialysis drug or biological product. We are soliciting

comments on this proposed methodology for a post-TDAPA add-on payment adjustment and its appropriateness for CY 2024 and future years.

(b) Example of the proposed post-TDAPA add-on payment adjustment calculation

Following the proposed methodology in the previous section, we are proposing to apply a post-TDAPA add-on payment adjustment to all ESRD PPS treatments beginning April 1, 2024, when the TDAPA payment period for *Korsuva*TM ends. We are proposing to calculate the amount of this post-TDAPA add-on payment adjustment based on the most recent available 12 months of utilization data for *Korsuva*TM and the most recent available 12 months of ESRD PPS claims data for this proposed rulemaking. We are also proposing that we would use updated data, if available, for the ESRD PPS final rule. We are proposing to apply the ESRD PPS patient-level adjustment factors for determining the amount of the post-TDAPA add-on payment adjustment for each ESRD PPS claim.

Based on the latest available data, which includes utilization of *Korsuva*TM from May 2022 through December 2022, we estimate that total expenditure for *Korsuva*TM in CY 2022 is \$3,150,910 and that 19,511,284 total ESRD PPS treatments were furnished during the same time period. Taking into account the existing ESRD PPS patient-level adjustment factors and the proposed TPEAPA as discussed in section II.B.1.g of this proposed rule, the reduction to the post-TDAPA add on payment adjustment to account for case-mix standardization for this time period is 0.900244. Accordingly, we would calculate a proposed case-mix adjusted post-TDAPA add-on payment adjustment for CY 2024 equal to $((\$3,150,910) / (19,511,284)) \times (0.900244) \times (0.65) \times (1.017) = \0.0961 . Estimates for the impact of this proposed post-TDAPA add-on payment adjustment for CY 2024 are included in section VIII.D.3 of this proposed rule.

(c) Considerations related to budget neutrality for the proposed add-on payment adjustment

As discussed earlier in this proposed rule, the ESRD PPS includes other add-on payment adjustments based on the authority in section 1881(b)(14)(D)(iv) of the Act, which are not

statutorily required to be budget neutral. In the case of existing add-on payment adjustments under the ESRD PPS, these generally account for costs that were not included in cost reports used for the construction of the ESRD PPS bundled payment. These include items that either did not exist at the time of the construction of the ESRD PPS bundled payment, like new drugs and equipment, or services that were not commonplace that the add-on payment adjustment is meant to encourage, like home dialysis training. We expect this increased payment would support ESRD facilities in providing the new renal dialysis drug or biological product to all beneficiaries for whom it is reasonable and medically necessary. We believe it is also important to support access to new renal dialysis drugs and biological products while minimizing the financial impact to beneficiaries, who incur a 20 percent coinsurance for renal dialysis services under the ESRD PPS.

As discussed above, we considered and are proposing this new post-TDAPA add-on payment adjustment in response to concerns that a sudden decrease in payment for certain new renal dialysis drugs and biological products after the end of the TDAPA period could negatively affect Medicare beneficiaries' access to such new renal dialysis drugs and biological products. Although we have noted that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, we do not believe that proposing a budget neutral payment adjustment would be appropriate for the post-TDAPA add-on payment adjustment. Because we are proposing to apply the post-TDAPA add-on payment adjustment to every ESRD PPS treatment, budget neutralizing this proposed add-on payment adjustment would effectively undo the adjustment and leave aggregate payments at the same level they would have been without an adjustment, which as we previously noted could negatively affect beneficiaries' access to such drugs and biological products. In contrast, applying this proposed add-on payment adjustment in a non-budget neutral manner would increase aggregate ESRD PPS expenditures to a level that reflects the most recent 12 months' utilization of the new renal dialysis drug or biological product, which we believe would

support beneficiary access. By applying the proposed post-TDAPA add-on payment adjustment in a non-budget neutral way, we would effectively maintain expenditures for these new renal dialysis drugs and biological products at 65 percent of the level of expenditures paid during the TDAPA period. We believe this approach would provide consistency and predictability in a way that would support beneficiaries' continued access to new renal dialysis drugs and biological products, while appropriately reducing expenditures for such drugs after the TDAPA period ends both for the Medicare program and for individual beneficiaries, as discussed earlier in this section. Accordingly, we are proposing that this post-TDAPA add-on payment adjustment would not be budget neutral. We welcome comments on the budget neutrality aspect of this proposal.

j. Proposal to Require “Time on Machine” Hemodialysis Treatment Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis

We are proposing certain new recordkeeping and cost reporting requirements for outpatient maintenance dialysis at proposed 42 CFR 413.198(b)(5). CMS proposes to require patient-level reporting on resource use involved in furnishing hemodialysis treatment in-center in ESRD facilities that would serve to apportion composite rate costs for use in the case-mix adjustment. Importantly, this new data would be used to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month level, which would enable a refined single-equation estimation methodology. The integrity of the ESRD PPS is dependent on our ability to monitor payment accuracy and make refinements to the payment system, as needed. Under this proposal, CMS would require ESRD facilities to report information on ESRD PPS claims for renal dialysis services about the duration of time in minutes that ESRD beneficiaries spend in center receiving hemodialysis treatment, also known as “time on machine” (hereafter referred to in this section as “time on machine”). We would use time on machine data to help us evaluate and monitor the accuracy of our payments for patient-level adjustment factors. CMS would also evaluate whether the data could be used to inform

future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which include patient age, body mass index (BMI), BSA, and co-morbidities such as sickle cell anemia. Finally, CMS would review the data for its potential to identify any disparities from a health equity perspective that may support proposing in future rulemaking new patient-level adjustment factors, including potential social determinants of health (SDOH) factors.

(1) Statutory Authorities for Recordkeeping, Cost Reporting, and Case-Mix Adjustments Under the ESRD PPS

Section 1881(b)(2)(B) of the Act generally directs the Secretary to prescribe in regulations any methods and procedures to determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals with ESRD, and to determine, on a cost-related or other economical and equitable basis, payment amounts for Medicare part B services furnished by such providers and facilities to individuals with ESRD. To that end, CMS promulgated 42 CFR 413.198,³⁴ which specifies certain recordkeeping and cost reporting requirements for ESRD facilities that meet the conditions for coverage under 42 CFR part 494.³⁵ The recordkeeping and cost reporting requirements at § 413.198 enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis and support the two-equation payment model that is currently used as the basis for the ESRD PPS.

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. We implemented this statutory requirement in § 413.235, which sets forth certain patient characteristics for which the per treatment ESRD PPS base rate may be adjusted, specifically

³⁴ We note that § 413.198 was promulgated prior to the establishment of the ESRD PPS. It was initially set forth in 1983 at 42 CFR 405.441 (48 FR 21254), to implement section 2145 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35). Section 405.441 was later redesignated in 1986 as 42 CFR 413.174 (51 FR 34790-01), and the requirements were moved again, from § 413.174 to § 413.198, in a reorganization of subpart H of part 413 (62 FR 43657).

³⁵ Likewise, under section 1881 of the Act, CMS established related data and information requirements at 42 CFR 494.180(h).

where those patient characteristics result in higher costs for ESRD facilities. The patient characteristics at § 413.235(a) include: patient age, body surface area, low body mass index, onset of renal dialysis (new patient), and co-morbidities. The Secretary is also authorized, under section 1881(b)(14)(D)(iv) of the Act, to apply such other payment adjustments under the ESRD PPS as the Secretary determines appropriate. Per 42 CFR 413.196, we publish notice of any proposed changes to payment adjustments, including adjustments to the composite rate,³⁶ in the **Federal Register**. We last updated the payment multipliers for the ESRD PPS patient-level adjustment factors in the CY 2016 ESRD PPS final rule (80 FR 68968, at 68973 through 68984), for age, BSA, low BMI, sex, four co-morbidity categories (that is, pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis. We also established payment adjustments for pediatric patients and for facilities treating a low-volume of patients with ESRD.

Finally, the proposal to collect and evaluate time on machine data would provide additional information concerning resource use to enable CMS to identify, assess, and address potential health disparities. This proposal therefore may support the Secretary's efforts to evaluate race and ethnicity data and provide recommendations for improving the quality of the data, as required under section 1809 of the Act, previously discussed in the CY 2011 ESRD PPS final rule (75 FR 49030 at 49108 through 49113).

We note that, if the proposed requirement to collect time on machine data were to be finalized as proposed, we would issue corresponding guidelines. Such guidance would provide instructions regarding the applicable administrative requirements for reporting a value code on an electronic claim, here value code D6, connected to the number of minutes of hemodialysis treatment provided in center in an ESRD facility. We further note that the National Uniform

³⁶ As explained in the CY 2011 ESRD PPS final rule (75 FR 49030 at 49032), the composite rate is the method by which CMS determines prospectively the amounts of payments for renal dialysis services furnished by providers of services and by renal dialysis facilities to individuals in a facility, and to such individuals at home. The composite rate is a single composite weighted formula that is combined with separately billable services under a single payment, adjusted to reflect patient differences in resource needs or case-mix.

Billing Committee (NUBC) has approved and is prepared for ESRD facilities' use of value code D6 on claim form CMS-1450 (UB-04) (OMB-0938-0997), to report the total number of minutes of hemodialysis provided during the billing period.

(2) Case-Mix Adjustments Background and the Two-Equation ESRD PPS Model

The ESRD PPS includes patient-level adjustments that adjust the ESRD PPS base rate for certain patient characteristics. The current ESRD PPS case-mix adjustments are derived from a case-mix adjustment model involving two equations. In the CY 2011 ESRD PPS final rule (75 FR 49083), we discussed the two-equation methodology used to develop the adjustment factors that would be applied to the ESRD PPS base rate to calculate each patient's case-mix adjusted payment per treatment. The two-equation approach used to develop the ESRD PPS included a facility-based regression model for services historically paid for under the composite rate as indicated in ESRD facility cost reports, and a patient-month-level regression model for services historically billed separately. One significant limitation, which in large part drove the development of the two-equation model, was that there was no way to reliably identify, using claims data, the costs for composite rate services—that is, items and services such as staff labor, dialysate, capital-related assets such as renal dialysis machines, and certain drugs and laboratory tests, that are used in the provision of outpatient maintenance dialysis for the treatment of ESRD and that were included in the composite payment system established under section 1881(b)(7) of the Act and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

In the CY 2016 ESRD PPS final rule, we updated the payment multipliers for the ESRD PPS patient-level adjustment factors for age, BSA, low BMI, sex, four co-morbidity categories (that is, pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis; we also established payment adjustments for pediatric patients and for ESRD facilities treating a low-volume of ESRD patients (80 FR 68968 at 68973 through 68984). In that CY 2016 ESRD

PPS final rule, we discussed and responded to a number of public comments in which commenters expressed concerns about the continued use of the two-equation model (80 FR 68974 through 68976). One comment from MedPAC suggested that CMS develop a one-equation model for the ESRD PPS. In response, we noted that the ESRD PPS is not currently able to utilize a one-equation method because ESRD facilities do not report charges associated with the components of renal dialysis treatment costs that vary across patients, such as time on machine. In other words, patient-level claims provide line item detail on the use of the formerly separately billable services, but do not provide any information regarding variation across patients in the use of the formerly composite rate services. In addition, we stated that we believed that capturing the resource cost for furnishing renal dialysis services is complex since Medicare has historically paid an ESRD PPS base rate (that is, composite rate payment) to account for those costs that were never itemized on a claim but were reported through the cost report (80 FR 68975 through 68976).

(3) Background on CMS Efforts to Explore the Use of “Time on Machine” Data to Refine the Case-Mix Adjustment Model

Interested parties, including MedPAC, have long expressed concerns about the complexity of the two-equation model underpinning the ESRD PPS and have questioned the validity of assuming that the composite rate costs for all patients at an ESRD facility are the same. Interested parties have encouraged CMS to develop a patient cost model that is based on a single patient-level cost variable that accounts for all composite rate and formerly separately billable services. Additionally, interested parties have expressed concerns that the existing case-mix adjusters might not correlate well with the current cost of renal dialysis treatment and have encouraged CMS to explore a refinement.

In response, CMS has explored the feasibility of collecting time on machine data on patient claims from ESRD facilities and the potential for using such data. These efforts include: a Technical Expert Panel (TEP) held on December 6, 2018, a Request for Information (RFI)

published in the ESRD PPS CY 2020 ESRD PPS proposed rule (84 FR 38399), and more recently an RFI published in the ESRD PPS CY 2022 proposed rule (86 FR 36322, 36399 through 36400). In addition, CMS issued sub-regulatory guidance in Transmittal 10368, from September 24, 2020, in an effort to begin collecting time on machine data, but it later rescinded that guidance.

(a) Technical Expert Panel (TEP) December 2018

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), a TEP was held on December 6, 2018, to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. In that CY 2020 ESRD PPS proposed rule, we discussed the purpose of the TEP and the topics that were discussed, including several data collection options.³⁷

In the CY 2020 ESRD PPS proposed rule, we noted that CMS's data contractor's pre-TEP analysis of CY 2016 cost report data showed that composite rate costs comprise nearly 90 percent of average total treatment costs, with capital, direct patient care labor, and administrative costs representing approximately 88 percent of total average composite rate cost per treatment. The data contractor provided examples of ways that longer duration of renal dialysis time might be associated with increased treatment costs, including utility costs, accelerated depreciation on equipment, and lower daily census counts, which, among other things, would result in increased per-treatment capital costs. The analysis suggested that additional labor hours for a patient with longer treatments on average could increase per-treatment labor costs, and that patients with increased use of dialysate and water treatment supplies or equipment likely have higher average per-treatment supply costs. We noted that, under current reporting practices, there are no data on the patient-and treatment-level variation in the cost of composite rate items and services. We explained that these findings underscore the

³⁷ The final TEP report from December 2018 and other materials can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.

importance of identifying variation in these costs to inform the development of a refined case-mix adjustment model.

CMS published the findings from the December 2018 TEP in a report dated June 2019.³⁸ The 2018 TEP report provided examples of ways that extended treatment duration could affect cost components. First, an imputed cost per treatment was calculated using a combination of treatment duration data from CROWNWeb³⁹ (now the ESRD Quality Reporting System, or EQRS) and facility cost per-minute data from cost reports to infer differences in cost report costs across patient-months. An average interquartile range of 34.6 minutes was observed from CROWNWeb duration data, indicating significant within-facility variation in dialysis treatment time. Significant variation in average imputed cost per hemodialysis sessions also was observed, with an across-facility interquartile range of \$62.62. Overall, it was found that cost report costs increased with longer treatment times, and this pattern was consistent for the individual cost report components as well. Facilities with a higher proportion of beneficiaries receiving treatments ≥ 4.5 hours duration were found to have higher average costs for each cost component, with the exception of cost report drugs.⁴⁰

CMS presented further discussion into collection of time on machine data for each dialysis session in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), where we further identified this potential data set as a singular option that would provide sufficient data to develop a refined case-mix adjustment model. If renal dialysis session time were reported for each renal dialysis treatment, cost report and treatment-level data could be integrated to infer differences in composite rate costs across patients. In this paradigm, patient-level differences in

³⁸ The final TEP report from December 2018 is found directly at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Summary-Report-June-2019.pdf>.

³⁹ In 2008, CMS introduced an electronic Web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) which was designed to collect clinical performance measures data from dialysis facilities (73 FR 20370, at 20372). CROWNweb is now “EQRS”—that is, the ESRD Quality Reporting System (OMB Control Number 0938-1289).

⁴⁰ Acumen LLC. ESRD PPS Case-Mix Adjustment Technical Expert Panel (TEP). Slide Presentation Slide 42. December 2018. See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf>.

composite rate costs could be attributed to two discrete categories: differences due to renal dialysis treatment duration (measured in units of time); and, differences unrelated to treatment duration. To alleviate concerns from interested parties, we noted that time on machine data would not be used to directly adjust ESRD PPS payment, rather, it would be used to apportion composite rate costs (currently only observable at the facility level to the patient or treatment level) for use in the case-mix adjustment. Time on machine data would allow for a higher proportion of composite rate costs to be allocated to patients with longer renal dialysis treatment times, and ultimately inform CMS refinements to existing patient-level adjusters, including age and comorbidities.

We further explained that, in the December 2018 TEP, the data contractor proposed two approaches to collect time on machine data: (1) Use existing data from Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) (now EQRS) on delivered renal dialysis minutes during the monthly session when a laboratory specimen is drawn to measure blood urea nitrogen (BUN); or (2) have ESRD facilities report time on machine data on Medicare claims. For the latter, we suggested that time on machine data could be reported by using a new HCPCS or revenue center code to indicate units of treatment time for each renal dialysis treatment or by updating the definition of the existing revenue center code for renal dialysis treatments so that the units correspond to treatment time instead of the number of treatments. We noted that ESRD facilities already reported to CMS a single monthly treatment time in CROWNWeb for in-facility treatments, indicating that ESRD facilities currently collect time on machine data.⁴¹ Moreover, we stated that we were aware that many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every renal dialysis treatment, minimizing additional burden of reporting this metric on claims.

⁴¹Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Payment Year (PY) 2021 Measure Technical Specifications. Page 23. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2021-TechnicalSpecifications-.pdf>.

The December 2018 TEP participants preferred that the data be collected on Medicare claims (84 FR 38398). They did not support using the then-existing CROWNWeb data for time on machine data, as there were too many questions about its completeness and timeliness. They agreed that if time on machine data is collected on claims that it should be reported in actual minutes dialyzed and not, for example, in 15-minute increments. We explained that the TEP participants cautioned that reporting time on renal dialysis on the claims would place additional burden on ESRD facilities. However, we stated that we believed that, for ESRD facilities with EHRs, the burden associated with the collection of renal dialysis treatment time is expected to be small and temporary, because the information is already being collected. We noted that collecting time on machine data could be difficult to accomplish for ESRD facilities that do not use EHRs. Lastly, we stated that some participants maintained that certain factors related to patient complexity—such as comorbidities and mental health status—that are associated with treatment costs are unrelated to treatment duration.

(b) Request for Information (RFI) in the CY 2020 ESRD PPS Proposed Rule

In addition to presenting the findings from the December 2018 TEP, we solicited comments in the CY 2020 ESRD PPS proposed rule (84 FR 38399) on the option of collecting time on machine data. As discussed in the CY 2020 ESRD PPS final rule (84 FR 60648, 60782), commenters responding to the RFI opposed the use of time on machine data, maintaining that other factors were more directly related to cost of treatment. Commenters claimed that many subgroups of patients are challenged to stay on renal dialysis for the prescribed treatment time because of their physical status or other limitations, leading to more frequent treatment and/or higher costs related to patients' special circumstances and comorbidities and not to treatment duration. With regard to patient-level factors contributing to high costs of care, commenters expressed that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care and opposed the use of time on machine data as a single, patient-level factor to estimate variation in composite rate costs. Some commenters expressed the objection

that use of this measure would not be productive because there was great homogeneity in treatment times across patients.

(c) CMS Sub-Regulatory Guidance in Transmittal 10368 (September 24, 2020) (Now Rescinded)

In Transmittal 10368, published September 24, 2020, CMS instructed its Medicare Administrative Contractors (“MACs”) to implement a new value code D6, which reflects the total number of minutes of dialysis provided during the billing period. See Transmittal 10368, CR 11871 (*Changes to the End Stage Renal Disease (ESRD) PRICER to Accept the New Outpatient Provider Specific File Supplemental Wage Index Fields, the Network Reduction Calculation and New Value Code for Time on Machine*), effective January 1, 2021. At the same time, CMS announced a new requirement for ESRD facilities to report value code D6 on ESRD claims, for in-facility or home hemodialysis maintenance, training, or retraining treatments. Shortly after making these contractor directions public, CMS issued a Medicare Learning Network (MLN) Matters guidance document (MLN Matters No. MM11871) advising ESRD facilities of the new requirement to include treatment time on claims. However, after a large dialysis organization submitted a petition⁴² pursuant to the HHS Good Guidance Practices Regulation,⁴³ HHS issued a finding that notice-and-comment rulemaking was required for CMS to impose such a requirement. Consequently, CMS rescinded Transmittal 10368 and replaced it with Transmittal 10576, dated January 20, 2021, withdrawing the requirement for reporting time on the dialysis machine with value code D6. Although the guidance to report time on machine data was rescinded, the value code D6 for the time on machine in minutes remains approved by the NUBC and remains on the CMS claim form CMS-1450 (UB-04) (OMB-0938-0997), in a deactivated status.

(d) Request for Information (RFI) in the CY 2022 ESRD PPS Proposed Rule

⁴² The petition (dated December 23, 2020) is attached as Exhibit A to HHS’s petition response (January 8, 2021) which can be found at <https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf>.

⁴³ The HHS “Good Guidance Practices” final rule appeared in the **Federal Register** on December 7, 2020 (85 FR 78770), and was later rescinded July 25, 2022 (87 FR 44002).

CMS revisited the topic of time on machine in the 2020 TEP and discussed the case-mix adjusters.⁴⁴ Interested parties continued expressing concerns that the existing case-mix adjusters might not align with resource-intensive patient-level services such as isolation rooms, behavioral issues, or neurocognitive issues. We sought additional public input in the ESRD PPS CY 2022 proposed rule, requesting information on the methodology used to calculate the case-mix adjustment (86 FR 36322, 36399 through 36400), in particular, the methodology to collect data to reflect patient-level differences in composite rate costs, including the use of a value code to collect time on machine on the claim.⁴⁵

We received similar comments on this RFI to those expressed in response to the CY 2020 ESRD PPS proposed rule. As discussed in the CY 2022 ESRD PPS final rule, commenters cited concerns that apportioned composite rate costs (such as labor and capital related costs) from the cost reports, used in the case-mix adjustments, were currently only observable at the facility-level and did not include patient or treatment level variations.

Similar to previously mentioned concerns regarding the collection of time on machine data, commenters suggested this data element would be burdensome and complex (especially for those dialyzing at home), and would not identify high-cost patients. They stated that what little variation might be identified would not be worth the burden of collecting the information. In addition, these commenters stated that ESRD facilities' staffing is based on prescribed time, not on the actual time a patient is on the machine. They stated that the prescription approach is the most rational way to determine staffing levels, because ESRD facilities do not have time on machine in advance. According to these commenters, ESRD facilities thus would only have the prescribing physician's prescription to use.

⁴⁴ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

⁴⁵ We published a summary of the responses to the CY 2022 ESRD PPS RFI (86 FR 36322, 36399 through 36400) for the current case-mix methodology in the ESRD PPS CY 2022 final rule (86 FR 61874, 61997) and provided greater detail on the CMS website at <https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf>.

A provider advocacy organization opposed the use of time on machine data for purposes of ESRD PPS primarily because certain patients benefit from shorter, more frequent dialysis, such as patients with catheter-related access issues, non-compliant patients, patients with chronic pain or diarrhea, and patients suffering from certain comorbidities. They expressed significant concern that use of time on machine data for differentiating treatment cost variability creates inappropriate incentives for certain ESRD facilities to “game the system” by: (1) putting patients on renal dialysis longer than necessary; or (2) placing patients on the cheapest dialyzer and keeping them on it for all five possible hours of dialysis. Another small renal dialysis organization agreed, pointing out that most renal dialysis treatments, regardless of time, will have similar composite rate costs. In other words, they asserted that if a treatment is 3.5 hours compared to 5 hours, the composite rate costs for those treatments will be very similar. The only difference in cost between those two treatments would be 1.5 hours more use of utilities, dialysate and bicarbonate solution, machine depreciation, and a small amount of labor to check on the patient. The vast majority of labor for renal dialysis treatments is putting the patient on and taking the patient off of dialysis. Therefore, in both of the above scenarios, the commenter asserted that cost will remain the same. Further, they pointed out that some patients will not remain for their full renal dialysis treatment, and they generally cannot force a patient to remain for their full prescribed treatment time. Therefore, in their view, using actual treatment time for cost allocation is not realistic.

A small renal dialysis organization within a large non-profit health system commented that reporting treatment times would be difficult and confusing and identified many factors that would need to be outlined by CMS including: When does renal dialysis time start; what happens when a patient chooses to discontinue their treatment early, or has complications resulting in reduced treatment time; what happens when an ESRD facility inadvertently does not track time for a treatment; how does this information get included on a claim; and how ESRD facilities would need to train staff on how to count and track time. They also expressed concern about the

reporting of time on machine creating opportunities for ESRD facilities to game the system by having the renal dialysis run a few extra minutes to move into the next highest level.

Several commenters recommended changes or removal of the case-mix adjusters, including refinement of the age and weight (BSA and BMI) adjustments and removal of the comorbidity adjustments, based on declining frequency of claims containing comorbidities. Moreover, some comments recommended removal of the comorbidity adjustments, because they report the adjustments are not utilized. They recommended CMS refine the age and weight (BSA and BMI) adjusters to better capture and designate higher cost patients. Many commenters expressed the belief that the comorbidity categories no longer protect beneficiary access and no longer correlate with increased costs. A non-profit renal dialysis association recommended that CMS minimize resources devoted to adjusters, providing only the minimum needed to deliver quality patient care, restore significant funding to the ESRD PPS base rate for the benefit and care of all beneficiaries, and focus retained adjusters only on those that are clearly linked to patient cost of care or clear barriers to access. Specifically, they recommended that: CMS retire the remaining comorbid case mix adjusters; revise the weight adjusters to maintain a low-BMI adjuster; create a high-BMI adjuster; eliminate the BSA adjuster; retire the age adjuster (which they believe is not methodologically sound and does not resonate with clinician or renal dialysis facility experience of care); maintain the adjuster for low volume facilities; consider expanding the adjuster to a second tier of facilities providing fewer than 6,000 treatments per year; eliminate the rural adjuster; and maintain the onset of renal dialysis adjuster to support the resource intensive needs of patients starting dialysis. Other commenters stated it would be too preliminary to eliminate the case-mix adjusters wholesale; they recommended that CMS initiate a discussion of the adjusters that are true drivers of high costs and how the use of adjusters can be operationalized for practical purposes. One payment adjustment that was universally supported by commenters was the onset adjustment.

MedPAC recommended that CMS develop a one-equation regression model in place of the current two-equation model currently used as the basis for the ESRD PPS. MedPAC also recommended that CMS consider removing the comorbidity adjustments and revise the body size adjustment. MedPAC further recommended that CMS address the inherent correlation between BSA and BMI by jointly estimating the association of BSA and BMI with treatment cost. Both BSA and BMI are calculated based on patient height and weight. MedPAC's analyses found that BSA and BMI values are correlated such that patients with low BMI also tend to have low BSA, and that these variables have a joint effect on treatment costs that is different from the sum of independent effects as currently implemented. We reiterated our current inability to implement such a model given the absence of data on the charges associated with the components of renal dialysis treatment costs that vary across patients in the use of the formerly composite rate services. A non-profit renal dialysis association agreed with MedPAC.

(4) Health Equity Considerations Supporting the Proposed Collection of Time on Machine Data

CMS prioritizes expansion of the collection, reporting, and analysis of standardized data as a key means to advance health equity.⁴⁶ By increasing our understanding of the needs of those we serve, CMS aims to ensure all individuals have access to equitable care and coverage. CMS's proposal to collect time on machine data supports these priorities. CMS believes the proposed data reporting requirements would support our ability to assess whether, and to what extent, our programs and policies may perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities.

As noted earlier, as part of CMS's December 2018 TEP and in the ESRD PPS CY 2020 final rule, CMS's EQRS data (formerly collected under CROWNWeb) is reported once per patient-month. Thus, CMS's proposal to collect time on machine data, which would require duration of treatment data reported for every renal dialysis treatment, would provide a more

⁴⁶ <https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity>.

granular set of standardized data for analyzing (and, potentially, apportioning) composite rate costs for use in the case-mix adjustment. CMS would also look to time on machine data as a source to monitor claims data and identify disparities in care that could be mitigated by potential future adjustments that would incentivize equitable care within the framework of the ESRD PPS.

We note that ESRD PPS reform is an on-going multi-year effort to refine payment adjustments and methodologies under the ESRD PPS. Section 1881(b)(2)(B) of the Act provides that the Secretary shall prescribe in regulations any methods and procedures to determine the amounts of payments to be made for part B services (which include renal dialysis services), on a cost-related basis or other economical and equitable basis. Furthermore, section 1881(b)(14)(D) of the Act requires the ESRD PPS to include a payment adjustment based on case mix that may take into account various patient characteristics and other appropriate factors.

Since the establishment of the ESRD PPS in the CY 2011 ESRD PPS final rule (75 FR 49030), CMS has been engaged in ongoing monitoring and analysis of the ESRD PPS. CMS publishes these monitoring results regularly.⁴⁷ CMS's monitoring activities have involved analysis of ESRD facility cost reports and patient claims to determine the most accurate adjustments and methodologies as well as to identify trends in beneficiary health outcomes. Similarly, CMS notes that this proposal to collect more-detailed standardized data (that is, the proposed time on machine reporting) than is presently available for analysis supports our ability to evaluate potential disparities in health care provided to our beneficiaries.

Presently, CMS adjusts the per-treatment ESRD PPS base rates to account for variation in the case mix, as set forth in 42 CFR 413.235. These adjustments account for patient age, BSA, low BMI, onset of renal dialysis (new patient), and comorbidities (for example, sickle cell anemia), as specified by CMS. The data and information that inform these adjustments are derived from cost reports, which are submitted to CMS on the facility level. However, we note

⁴⁷ Since the implementation of the ESRD PPS in January 2011, CMS has monitored outcomes, through a claims-based monitoring program, for Medicare beneficiaries receiving outpatient maintenance dialysis. See <https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/esrd-claims-based-monitoring>.

that time on machine data would be provided to CMS at the patient level, on patient claims. This change would shift CMS's focus to a more patient-centered paradigm. We believe time on machine data would provide the insights we need to develop (and propose) potential amendments to the payment multipliers for the current, and potential future, patient-level adjustments, including new SDOH factors or health conditions (such as profound post-dialytic exhaustion) as patient-level adjustments. More immediately, however, time on machine data would significantly enhance CMS's insight into whether our current payment adjusters are appropriately aligning with actual resource use for individuals and communities who are underserved or disadvantaged and who may have multiple patient-level characteristics that necessitate longer renal dialysis times.

For example, CMS is aware of anecdotal evidence and published studies showing that patients with the comorbidity of sickle cell anemia may need a longer renal dialysis treatment time as well as additional resources from medical staff to attend to the manifestations of sickle cell that occur during dialysis. In fact, renal dialysis patients with sickle cell anemia may have frequent pain attacks during the actual renal dialysis treatment.⁴⁸ Such an attack, known as a vaso-occlusive pain crisis, precipitates a series of medical interventions involving intravenous fluids, analgesia, as well as the treatment of any precipitant and/or acute comorbid state.⁴⁹ CMS would be able to use time on machine data for patients with sickle cell anemia to evaluate its alignment with the patient-level adjuster for the corresponding co-morbidity.

In addition to re-evaluating and potentially updating the payment multiplier for the patient-level adjuster for the co-morbidity of sickle cell anemia, CMS anticipates that there could be other instances where patients need more time on renal dialysis to avoid uncomfortable post-dialytic sequela, such as profound post-dialytic exhaustion. In instances of profound

⁴⁸ Benjamin Jacob et al. Management of the Dialysis Patient with Sickle Cell Disease (Seminars in Dialysis 14 July 2015, <https://doi.org/10.1111/sdi.12403>).

⁴⁹ Derebail VK, Lacson EK Jr, Kshirsagar AV, Key NS, Hogan SL, Hakim RM, et al.: Sickle trait in African-American hemodialysis patients and higher erythropoiesis-stimulating agent dose. *J Am Soc Nephrol* 25: 819– 826, 2014.

post-dialytic exhaustion, for example, CMS would evaluate the forthcoming time on machine data for the potential correlations between additional hemodialysis treatment time and decreased incidence of profound post-dialytic exhaustions, which may have cost implications. We are aware that there may be a need for a future patient-level payment adjuster associated with post-dialysis fatigue.

(5) Proposed Requirement for Reporting Time on Machine Data to Evaluate Accuracy of Current Payment Adjusters Aligned with Resource Use

We propose to require patient-level reporting on resource use involved (time on machine) in furnishing hemodialysis treatment in-center in ESRD facilities, which would serve as a proxy to apportion composite rate costs (capital, labor, and administrative costs, as well as drugs, laboratory tests, and supplies necessary to administer the dialysis treatment) for use in the case-mix adjustment. This would allow us to more precisely estimate the average costs of the various above-mentioned components of a renal dialysis treatment that cannot currently be captured because payment for these items is bundled, and claims data do not contain detail on the use of these items and services. CMS would review the patient-level resource use data, including time on machine data, to evaluate and monitor the accuracy of the methods and procedures, including the patient-level adjustment factors, enhancing the integrity of the ESRD PPS. In addition, CMS would evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which may include age, BMI, BSA, and co-morbidities such as sickle cell anemia. Finally, CMS would review the data for its potential to identify any disparities from a health equity perspective and to support the future proposal of any new patient-level adjustment factors, including potential SDOH factors. We note that such data may also be used to inform potential future refinements to the facility-level adjustment factors, if appropriate. Per 42 CFR 413.196, we would publish notice of any proposed changes to payment adjustments, including adjustments to the composite rate, in the **Federal Register**.

(a) Proposed changes to 42 CFR 413.198

We propose to amend 42 CFR 413.198 by adding language at § 413.198(b)(5) that would require each ESRD facility to submit data and information, under existing paragraph § 413.198(b)(3) describing allowable costs, of the types and in the formats established by CMS, for the purpose of estimating patient-level and facility-level variation in resource use, such as data and information on the duration of hemodialysis treatment (that is, time on machine data) involved in furnishing hemodialysis treatment in center in an ESRD facility. For additional context, we note that, under § 413.198(b)(3), allowable cost is the reasonable cost related to renal dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the ESRD facility in furnishing the renal dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. Reasonable cost includes both direct and indirect costs and normal standby costs.

We also propose to update § 413.198(a) by adding a reference to section 1881(b)(14) of the Act to acknowledge the statutory provisions for the ESRD PPS.

(b) Additional Considerations for the Proposed Reporting of Time on Machine Data

CMS reviewed past comments from its TEPs and RFIs and gave additional consideration to the approach of our now-rescinded sub-regulatory guidance in Transmittal 10368 and to the complexities of reporting the number of minutes of hemodialysis treatment on patient claims. With this background in mind, we further refined our proposed requirements at proposed § 413.198(b)(5) in a way that would result in the reporting of the most useful, high value data.

In light of past comments questioning the feasibility and accuracy of time on machine reporting for home dialysis patients, we are proposing a reporting requirement that would only apply to patients receiving an in-center hemodialysis treatment. We believe this approach would ensure greater uniformity to the recording process and thus greater consistency in the data

reported. We note that Chapter 11 of the Medicare Benefit Policy Manual at section 10.A.1,⁵⁰ defines “hemodialysis” as the process by which blood passes through an artificial kidney machine and the waste products diffuse across a manmade membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient’s body. Hemodialysis is accomplished usually in 3 to 5 hour sessions, 3 times a week.

CMS also considered past comments responding to its RFI in the CY 2020 ESRD PPS final rule (84 FR 60648, 60782) regarding patient-level factors that contribute to high costs of care. CMS agrees with commenters that expressed that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care.

We also considered comments from a provider advocacy organization that opposed the use of time on machine data for purposes of ESRD PPS primarily because, they stated, certain patients benefit from shorter, more frequent dialysis, such as patients with catheter-related access issues, non-compliant patients, patients with chronic pain or diarrhea, and patients suffering from certain comorbidities. Still other commenters claimed that many subgroups of patients are challenged to stay on renal dialysis for the prescribed treatment time because of their physical status or other limitations, leading to more frequent treatment and/or higher costs related to patients’ special circumstances and comorbidities and not to treatment duration. The commenters noted that, in both of the above scenarios, costs would remain the same. Further, they pointed out that some patients will not remain for their full renal dialysis treatment, and short of using restraints, there is nothing that can be done to force a patient to remain for their full prescribed treatment time. Therefore, in their view, using actual treatment time for cost allocation is not realistic.

CMS agrees that the payment multipliers for patient-level adjusters should be grounded in strong evidence, and we recognize that each patient will have unique needs, with some being

⁵⁰ Section 10.A.1 of Chapter 11 of the Medicare Benefit Policy Manual also directs the reader to review section 50.A.1 of Chapter 11 for payment information.

more costly to treat and others with fewer costs, given their medical backgrounds. We emphasize and again clarify that, under this proposal, time on machine data would not be directly used to determine payment for renal dialysis services, nor would higher payments be made for longer treatments.

CMS also considered comments suggesting that a “time on machine” data element would not identify high-cost patients and comments suggesting such a data element would not be productive given the commenter’s assertion that there was great homogeneity in treatment times across patients. One commenter noted that the vast majority of labor for renal dialysis treatments is putting the patient on and taking the patient off of dialysis, and another commenter pointed out that most renal dialysis treatments, regardless of time, will have similar composite rate costs. (In other words, they asserted that if a treatment is 3.5 hours compared to 5 hours, the composite rate costs for those treatments will be very similar. The only difference in cost between those two treatments would be 1.5 hours more use of utilities, dialysate and bicarbonate solution, machine depreciation, and a small amount of labor to check on the patient.) We agree with commenters that treatment times and costs may be similar across most patients based on our analysis and the comments of TEP participants. However, we would not expect to find that ESRD facilities are treating ESRD patients in a homogeneous fashion, but on a case-by-case basis determined by patient-centered plans of care. We note that a review of CY 2016 cost report data, conducted as part of the December 2018 TEP,⁵¹ showed that overall costs of renal dialysis services (within the ESRD facility cost reports) increased with longer treatment times, and that this pattern was consistent for the individual cost report components.

We anticipate that the data that would become available under the proposed requirement, if finalized, for reporting time on machine data would provide insight into meaningful, measurable variabilities in certain costs associated with patient-level characteristics.

⁵¹ As presented on Slide 42 from the December 2018 TEP, overall costs of renal dialysis services (within the ESRD facility cost reports) increased with longer treatment times. See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf>.

The significance of the proposed time on machine data is dependent upon the collection of data from a preponderance of patient claims for in-facility hemodialysis. While the majority of patient claims may come from patients with similar profiles and treatment plans, the needs of the more complex and resource-intensive patients can only be identified by CMS through the collection of patient-level data from across the ESRD PPS patient population. Complex and resource-intensive patients are frequently encountered in the ESRD dialysis treatment setting, but it is not possible to obtain precise estimates of the higher costs of these patients' hemodialysis treatments from currently reported data. Cost reports and claims are the two data sources from which per treatment costs can be estimated. Since cost reports aggregate data at the facility level, patient-level differences in resource use are not detectable as higher medical needs, and related costs are masked by averages. Further, analysis of claims data from 2016 found that roughly 99 percent of ESRD facilities reported 10 or fewer distinct charge values across all patients and treatment modalities.⁵² Routinely collected, ESRD patient population-based data on time on machine for each in-facility hemodialysis treatment would enable CMS to assess variation in the use of composite rate items and services at the patient level and to identify high-need and high-cost patients. In addition, the proposed time on machine data set would enable CMS to further determine what trends or causal relationships may exist between certain patient-level characteristics and the number of minutes of hemodialysis treatment received by such patients. CMS would evaluate whether specific patient characteristics are associated with increased length of dialysis treatment, which contribute to cost.

We also considered comments that the costs to ESRD facilities for providing dialysis treatment could be better measured by looking at costs based on prescribed time, and not on the

⁵² See page 9 of the December 2018 TEP Report at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Summary-Report-June-2019.pdf>. See also Slide 27 from the December 2018 TEP Presentation at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf>. And see Slide 30 from the December 2019 TEP Presentation at <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2019.pdf>

actual time a patient is on the dialysis machine. The commenters stated their view that looking to prescribed time(s) would be the most rational way to determine staffing levels (and costs), because ESRD facilities plan for dialysis session length based on the prescribed time. Although CMS recognizes ESRD facilities' labor practices to align staffing with the stated prescription times, CMS is concerned that, for some patients, their prescription times are not aligning with actual usage and thus may not be the best predictor of ESRD facilities' costs. For example, we are aware that patients who experience severe itching or have certain psychological disorders may be less likely to receive dialysis for the full prescribed time. For such patients, only the collection of time on machine data for the number of minutes of hemodialysis treatment received would facilitate CMS's understanding of their complex needs and the implications for the ESRD PPS. For such patients, a pattern of shorter treatment times may ultimately result in worse patient outcomes and higher patient costs to the ESRD facility as well as to Medicare. CMS is also aware that patients with certain characteristics, such as higher BSA quartiles, may be more likely to need longer dialysis times.⁵³ Additionally, CMS has been made aware of instances in which ESRD facilities may avoid treating complex patients or patients with higher costs generally (thereby favoring average or lower cost patients). We note that prescribed dialysis times would not provide insight into costs for dialysis sessions for patients whose individual needs or circumstances might necessitate a dialysis treatment time that differs in practice from the prescribed dialysis time. Therefore, identifying actual resource usage, as correlated with the needs, health outcomes, and patient-level characteristics of complex patients would enable CMS to better align the payment multipliers with resource use within the ESRD PPS.

We anticipate that our proposed requirement would generate the data we would need to evaluate a potential adjustment of the payment multipliers for patient level adjustments, thereby allowing us to counteract possible financial disincentives to serving those patients. We would

⁵³ See slide 31 from the 2020 ESRD TEP presentation, which can be found here: <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf>.

expect that such adjustments may thereby enhance access to renal dialysis services for such resource-intensive patients. We also believe that collecting time on machine data is preferable to collecting prescribed times, since we recognize that patients' actual experiences do not always align with their doctors' orders.

Finally, we considered the comments by a small renal dialysis organization within a large non-profit health system that reporting treatment times would be difficult and confusing and that identified many factors that would need to be outlined by CMS including: When does renal dialysis time start; what happens when a patient chooses to discontinue their treatment early, or has complications resulting in reduced treatment time; what happens when an ESRD facility inadvertently does not track time for a treatment; how does this information get included on a claim. We recognize that a new reporting requirement will require uniformity in its implementation across ESRD facilities. We note that the proposed "time on machine" requirement is for the reporting of the number of minutes of hemodialysis treatment a beneficiary receives, and it refers to only the minutes (reported in whole minutes) spent dialyzing, while the patient is connected to the dialysis machine. If the proposed requirement were to be finalized, we would address such details in operational guidance.

(c) Using a Medicare Claims Data Field to Report Time on Machine Data

We propose that ESRD facilities report the number of minutes of hemodialysis treatment received in center in an ESRD facility using the D6 value code on the Medicare 72X type of bill (TOB) that is part of the CMS claim form CMS-1450 (UB-04) (OMB-0938-0997).⁵⁴ While our proposal limits the time on machine reporting requirement to in-center claims, to address the

⁵⁴ We considered collecting relevant time on machine duration of treatment data through the ESRD Quality Reporting System (EQRS), but we did not propose this approach due to concerns that interested parties raised — which we discussed in the December 2018 TEP and in the ESRD PPS CY 2020 final rule — that CROWNWeb (now EQRS) data is not reflective of typical patient treatment duration throughout the month. We note that EQRS data is reported once per patient-month and thus would include fewer observations than duration of treatment data reported for every renal dialysis treatment. It could therefore be less reliable for the purposes of monitoring and evaluating patient-level resource use, as well as for the purposes of apportioning composite rate costs for use in the case-mix adjustment. We further note that EQRS data are submitted on a voluntary basis and reflect a point in time each month for each facility and thus do not capture the full range of variation that ESRD facilities experience with patients over time.

concerns raised by interested parties about the burden and complexity of home dialysis reporting, we note that time on machine for home dialysis data could nonetheless be voluntarily reported using the D6 value code on claims.

CMS further notes that the proposed time on machine data requirement would be collected on Medicare 72X claims. This approach would address long-standing concerns, including such concerns raised by MedPAC and other interested parties, that CMS should move to a one-equation model. CMS agrees with interested parties that a single-equation model, to be constructed at the patient level, would reduce the complexity of the current model and would better align payment with costs. The current two-equation model's payment adjusters are derived using weighted averages of the coefficients from the facility-level and patient-level equations. Because the composite rate items currently compose roughly 90 percent of the payment, we are seeking a more detailed understanding of patients' utilization of such treatment resources. We anticipate that the time on machine data would provide a useful proxy for these composite rate items.

Furthermore, CMS notes that its proposal to collect time on machine data on patient claims would address past comments on whether such a reporting requirement could create perverse incentives for ESRD facilities to amend actual reported time on machine. Another past commenter expressed concern about whether an ESRD facility might have the renal dialysis run a few extra minutes to increase the payment. However, we note that requiring the reporting of time on machine data on a claim, by definition, would involve an attestation that the information submitted is correct and that the items presented represent medically necessary expenses. The False Claims Act (31 U.S.C. 3729 to 3733) establishes civil liability for knowingly presenting a false or fraudulent claim to the government for payment.

We note that, if the proposed requirement to collect duration of treatment data were to be finalized, we would then issue operational guidance in support of the requirement. Such guidance would describe the applicable instructions for reporting a value code (in this case, the

D6⁵⁵ value code) connected to the number of minutes of hemodialysis treatment provided to a patient in center.

(d) Proposed Use of Time on Machine Data for the ESRD PPS

We emphasize and again clarify that, under this proposal, time on machine data would not be directly used to determine payment for renal dialysis services, nor would higher payments be made for longer treatments. Rather, time on machine data would allow for patient-specific calculation of costs for composite rate services, including labor costs, costs for the use of renal dialysis machines and related equipment, and costs for such items as dialysate and other essential supplies. In this way, time on machine data would be used to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month level, which would enable a refined, single-equation estimation methodology. The refined, single-equation regression analysis (currently under development) would still be used to determine the inclusion/exclusion and magnitude of payment multipliers for patient-level case-mix flags that are associated with higher costs. Final payment adjustments would still only depend on existing patient-level case-mix adjusters, rather than a factor directly derived from time on machine data.

(e) Request for Information About Effective Date

We are proposing a January 1, 2025, effective date for this new reporting requirement. We are aware that all ESRD facilities record the time a patient has received hemodialysis treatment into a patient's medical record, and that, for most ESRD facilities, this time is automatically recorded into the patient's electronic health record (EHR). We further understand that ESRD facilities are able to transfer data from EHRs into the patient-specific claims that are submitted to Medicare for payment. However, we recognize that some ESRD facilities with limited resources may need to make modifications to their record keeping and reporting systems

⁵⁵ Value code D6 on claim form CMS-1450 (UB-04) (OMB-0938-0997), for reporting the total number of minutes of dialysis provided during the billing period.

to facilitate the transfer of a patient's recorded hemodialysis treatment time in the patient's medical record to the Medicare claim. Although we did receive a past comment indicating that a facility's implementation time would involve training staff on how to count and track time, we do not expect that the manual recording of a patient's hemodialysis treatment time into their health record is widespread. Finally, we note that ESRD facilities are already reporting extensive information from patient EHRs into Medicare institutional claim form CMS-1450 (UB-04) (OMB-0938-0997), and we would not expect implementation to be overly burdensome to ESRD facilities. We recognize that some ESRD facilities would need to establish a new pathway from patient EHRs to the Medicare claim form, in addition to making simpler programming updates to add a field for the total number of minutes of dialysis provided during the billing period. Based on our findings in the TEP from December 2018, we anticipate that the implementation challenges that ESRD facilities might experience would be small and temporary, as a patient's time receiving dialysis treatment is already collected for the patient's medical record. We are seeking comment on whether an earlier effective date, such as January 1, 2024, is feasible and would provide ESRD facilities with adequate time to implement this new reporting requirement.

(6) Proposed technical change to 42 CFR 413.198

We are proposing to fix a typographical error in 42 CFR 413.198(b)(3)(iii), which currently refers to "luxury items or servicess". We are proposing to change this to "luxury items or services".

k. Proposed Clarification to TDAPA Average Sales Price (ASP) Policy

In the CY 2020 ESRD PPS final rule, we finalized a conditional policy for TDAPA payment based on the availability of ASP data (84 FR 60679). In that final rule, we explained that if drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on WAC or invoice pricing, we believed we would be overpaying for the TDAPA for those products. We stated that we

would no longer apply the TDAPA for a new renal dialysis drug or biological product if a drug manufacturer submits a full calendar quarter of ASP data into CMS within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product, but at a later point during the applicable TDAPA period specified in § 413.234(c)(1) or (2), stops submitting a full calendar quarter of ASP data into CMS. We explained that once we determine that the latest full calendar quarter of ASP is not available, we would stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters. For example, we stated that if we begin paying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data is made available to CMS by October 30, 2021 (30 days after the close of the 3rd quarter of paying the TDAPA), but a full calendar quarter of ASP data is not made available to CMS as of January 30, 2022 (30 days after the close of the 4th quarter of paying the TDAPA), we would stop applying the TDAPA for the product no later than June 30, 2022 (2 quarters after the 4th quarter of paying the TDAPA).

We adopted this conditional policy in order to avoid overpaying for the TDAPA on an ongoing basis and in order to ensure that TDAPA payment is based on the most appropriate data, that is, ASP. Specifically, we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38349) and final rule (84 FR 60680) that we were concerned about (1) increases to Medicare expenditures due to the TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for products eligible for TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS.

Our existing regulation at § 413.234(c) does not specifically address the application of the TDAPA conditional policy in situations in which the manufacturer of the new renal dialysis drug or biological product submitted ASP data to CMS and reported zero or negative sales. Zero or negative sales may occur for a variety of reasons, including no sales, recalls of a product, or repurchases of sold products. In the CY 2012 PFS final rule (76 FR 73296), CMS clarified that zero or negative values are valid for ASP, ASP units, and WAC. Therefore, when such a

scenario occurs for separately payable Part B drugs, we consider the submission of zero or negative sales to fulfill the reporting requirements of manufacturer ASP data to CMS as set forth in sections 1927(b)(3)(A)(iii) and 1847A(f) of the Act. We note that in situations when zero sales are submitted, CMS guidance⁵⁶ instructs the manufacturer to report “0.000” for the ASP and the number of ASP units. The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based either on the published WAC or invoice pricing (except under OPPS, where the payment allowance limit is 95 percent of the published average wholesale price (AWP)). In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication 100-04, Chapter 17, section 20.4 Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is 106 percent of the lesser of the lowest-priced brand or median generic WAC.⁵⁷ Therefore, for purposes of the TDAPA conditional policy, in circumstances where a manufacturer submitted ASP data reflecting zero or negative sales during the TDAPA period, we are clarifying that we consider CMS to have received the latest full calendar quarter of ASP data, and we would not discontinue TDAPA payment under the conditional policy in § 413.234(c). Consistent with the pricing methodologies for separately payable Part B drugs, we would set the TDAPA payment amount based on WAC, or if WAC is not available, invoice pricing, for the quarter in which zero or negative sales were reported.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Proposals and Application for CY 2024 Payment

1. Background

⁵⁶ https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP_Data_Collection_Validation_Macro_User_Guide.pdf.

⁵⁷ Medicare Claims Processing Manual Chapter 17, section 20.1.3 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>.

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new technologies. We established this add-on payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, we would provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning granted marketing authorization by the FDA on or after January 1, 2020; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular CY; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at § 412.87(b)(1) and related guidance; and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that we would use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

First, CMS considers the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: (1) a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; (5) an improvement in one or more activities of daily living; an improved quality of life; or (6) a demonstrated greater medication adherence or compliance; or,

- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payment adjustments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and ESRD facility settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. We would consider whether a

new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we would announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular CY. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular CY. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for certain new and innovative renal dialysis equipment or supplies. We stated that the TPNIES is paid for two calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Regarding the basis of payment for the TPNIES, in the CY 2020 ESRD PPS final rule, we finalized at § 413.236(e) that the TPNIES is based on 65 percent of the price established by the MACs, using the information from the invoice and other specified sources of information.

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular CY to the HCPCS Level II code application

deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY. In addition, a copy of the applicable FDA marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criteria, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354) that we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID-19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

After closely considering these issues, we proposed a revision to § 413.236(b)(6) in the CY 2021 ESRD PPS proposed rule to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.235(b), and finalized the exception as proposed in the CY 2021 ESRD PPS final rule. We finalized the same determination process for TPNIES applications for capital-related assets that are home dialysis machines as for all other TPNIES applications; that we will consider whether the new home dialysis machine meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. In accordance with § 413.236(c), we will only consider, for additional payment using the TPNIES for a particular CY, an application for a capital-related asset that is a home dialysis machine received by February 1 prior to the particular CY. If the application is not received by February 1, the application will be denied and the applicant is able to reapply within 3 years beginning on the date of FDA marketing authorization to be considered for the TPNIES, in accordance with § 413.236(b)(2).

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate.⁵⁸ We finalized that this amount would be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

⁵⁸ The CY 2023 TPNIES offset amount was \$9.79. CMS is proposing a CY 2024 TPNIES offset amount of \$9.96, as discussed in section II.B.1.e of this proposed rule.

We revised § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

We revised § 413.236(d)(2) to reflect that following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning within 3 years beginning on the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines.

2. Proposed Clarifications Regarding CMS's Evaluation of the TPNIES Eligibility Criteria

This section of the proposed rule discusses proposed clarifications to our policies for evaluating the TPNIES eligibility criteria under § 413.236(b).

a. Sequential Order of CMS Review of the TPNIES Eligibility Criteria (§ 413.236(b))

As stated previously, we consider whether a new renal dialysis supply or equipment meets the TPNIES eligibility criteria as part of the annual ESRD PPS rulemaking and announce the results in ESRD PPS final rule. To qualify for the TPNIES, an applicant must meet each of

the TPNIES eligibility criteria set forth in § 413.236(b)(1) through (6). An applicant that fails to demonstrate that it meets each of the six eligibility criteria is not eligible for the TPNIES.

In the CY 2021 ESRD PPS final rule, we focused our analysis of the TPNIES eligibility criteria on those that were not met. That is, for the TheraNova Dialyzer, we included our analysis of how the applicant did not meet the innovation criterion under § 413.236(b)(5), and for the Tablo® cartridge, we included our analysis of how the applicant did not meet the newness criterion under § 413.236(b)(2) and innovation criterion under § 413.236(b)(5) (85 FR 71444 through 71464). In the CY 2022 and CY 2023 ESRD PPS final rules, we expanded our analysis to include our determination as to whether the applicants met each of the six criteria. In doing so, we analyzed the TPNIES eligibility criteria in the sequence that is provided in § 413.236(b)(1) through (6) (86 FR 61889 through 61906 and 87 FR 67193 through 67216).

We clarify that our analysis of the TPNIES eligibility criteria would continue to proceed in sequential order. Specifically, in the annual ESRD PPS proposed rule, we would continue to summarize the information from the application regarding each of the six eligibility criteria and include any questions or concerns that we identify during our analysis of the application.

Based on information provided by the applicant and from public comments during the annual ESRD PPS rulemaking cycle, we would continue to analyze the TPNIES eligibility criteria in sequential order in the annual ESRD PPS final rule. However, the change that we are proposing is that once it has been established that one criterion has not been met, we would not discuss or make specific determinations on the subsequent criteria for that item in the annual ESRD PPS final rule. We note that the criteria set forth in § 413.236(b) are intentionally listed in the order in which they appear. The first criterion is foundational in that an equipment or supply that is not a renal dialysis service would not be paid for under the ESRD PPS and therefore would not fit within the TPNIES payment pathway. As such, it would not be pertinent to evaluate the remaining TPNIES criteria for that item. TPNIES criteria two through four are objective and not subject to interpretation in that they each require data evidence to demonstrate

newness, commercial availability, and the submission of a HCPCS application, respectively. The TPNIES innovation criterion under § 413.236(b)(5) requires the most significant CMS evaluation. Under our TPNIES policy and § 412.87(b)(1)(i), CMS is required to consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. In doing so, we consider various non-objective circumstances in our review of the TPNIES applications, including the state of the ESRD landscape and the particular challenges and vulnerabilities of patients with ESRD (86 FR 61905). We believe that it is prudent to reserve our in-depth analysis of the TPNIES innovation criterion only for applications that provide the necessary evidence to demonstrate that they meet the earlier foundational and objective TPNIES criteria.

As described previously in the background section of this proposed rule, the TPNIES innovation criterion in § 413.236(b)(5) incorporates the substantial clinical improvement criteria in the IPPS regulations at § 412.87(b)(1) for the new technology add-on payment (NTAP). This sequential approach for reviewing eligibility criteria is also in place for the NTAP pathway. The FY 2009 IPPS final rule (73 FR 48561 through 48563) discussed the way in which CMS evaluates the NTAP eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. The NTAP cost criterion is not applicable in analyzing TPNIES eligibility. However, consistent with our approach under NTAP, we believe that the most prudent use of CMS resources would be to reserve our analysis and determination regarding whether a new equipment or supply meets the TPNIES innovation criterion by representing a substantial clinical improvement over existing technologies until after we determine the new equipment or supply meets the earlier criteria.

Under this proposal, we would first determine whether an equipment or supply meets the renal dialysis service criterion in § 413.236(b)(1) and present our analysis of this first criterion in the final rule. In instances where CMS determines that § 413.236(b)(1) has been met, we would proceed in assessing the newness criterion in § 413.236(b)(2) and present our analysis of this second criterion in the final rule. In instances where CMS determines that § 413.236(b)(2) has been met, we would proceed in assessing whether the commercial availability criterion in § 413.236(b)(3) has either been met or the applicant expects that it will be met by January 1 of the particular calendar year deadline and present our analysis of this third criterion in the final rule. In instances where CMS determines that § 413.236(b)(3) has been met or the applicant expects that it will be met by January 1 of the particular calendar year deadline, we would proceed in assessing the HCPCS Level II code application criterion in § 413.236(b)(4) and present our analysis of this fourth criterion in the final rule. In instances where CMS determines that § 413.236(b)(4) has been met, we would proceed in assessing the innovation criteria in §§ 413.236(b)(5) and 412.87(b)(1) and present our analysis of this fifth criterion in the final rule. In instances where CMS determines that § 413.236(b)(5) has been met, we would proceed in assessing the non-capital-related asset (except home dialysis machines) criterion in § 413.236(b)(6) and present our analysis of this sixth criterion in the final rule. In instances where CMS determines that § 413.236(b)(6), as well as each of the five preceding criteria in § 413.236(b)(1) through (5) as discussed above have been met, the equipment or supply would qualify for and would be paid for under the ESRD PPS using the TPNIES per § 413.236(d) beginning in the year that is the subject of the rulemaking.

In summary, we are proposing to clarify that as CMS proceeds through the sequential analysis of the six TPNIES eligibility criteria in the ESRD PPS final rule for a particular equipment or supply, once we determine that the item has failed to demonstrate having met one of the eligibility criteria, the item would be ineligible for the TPNIES. We would limit our analysis in the final rule to the TPNIES criterion that is not met and any preceding criteria that

have been determined to have been met. We would not include the analysis of the remaining criteria in the final rule. If finalized, this policy would be effective January 1, 2024, and would apply to our analysis of TPNIES applications for CY 2025 payment.

b. Clarifications Regarding the TPNIES Newness Criterion (§ 413.236(b)(2))

As stated previously, applicants must meet the newness criterion in § 413.236(b)(2) to qualify for the TPNIES. CMS defines the TPNIES newness criterion at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. In this proposed rule, we wish to clarify two distinct aspects of the criterion that are consistent with our current TPNIES policies and would not represent any changes to the eligibility criteria: (1) the 3-year newness period and (2) FDA marketing authorization.

First, with respect to the 3-year newness period, we stated in the CY 2021 ESRD PPS final rule that by defining new as within 3 years beginning on the date of the FDA marketing authorization, we limit eligibility for the TPNIES to new technologies but allow prospective TPNIES applicants 3 years beginning on the date of FDA marketing authorization in which to submit their applications (85 FR 71410 through 71464).

To ensure that the timeframe during which a prospective TPNIES applicant is eligible to apply is clear, we are proposing to modify our regulation to specify that the applicant would have 3 years from the date of FDA marketing authorization to apply for the TPNIES, based on the date the application is submitted. This proposed modification is consistent with current policy, and while it is not a change in policy, we believe that clarifying the regulation text would help to eliminate any confusion about the 3-year newness period. As indicated in § 413.236(c), February 1 prior to the particular calendar year is the annual TPNIES application submission deadline. We are proposing to clarify that the 3-year newness period is only for submission of the complete application. An applicant does not have to ensure that the application is submitted and that CMS renders its determination through notice and comment rulemaking within the 3-year newness period. Specifically, we are proposing to revise § 413.236(b)(2) to clarify that

the equipment or supply is new if a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization.

Second, with respect to the requirement in § 413.236(b)(2) that the equipment or supply must have FDA marketing authorization, we clarify that an equipment or supply with FDA Exempt status would not meet the newness criterion and therefore would not be eligible for the TPNIES. As described on the FDA website, the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act established three regulatory classes for medical devices: Class I, Class II, and Class III. The three classes are based on the degree of control necessary to assure the various types of devices are safe and effective.⁵⁹ Most Class I and some Class II devices, as noted on FDA's website, are exempt from premarket notification (510(k)) requirements, subject to certain limitations.⁶⁰ As we stated in the CY 2023 ESRD PPS final rule, devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and effectiveness for the devices. For exempt devices, FDA has determined that a premarket notification is not required to provide a reasonable assurance of safety and effectiveness for the devices. However, generally a Class I or Class II device that is exempt from 510(k) requirements still must comply with certain regulatory controls (known as “general controls”) to provide a reasonable assurance of safety and effectiveness for such devices. In limiting the TPNIES policy to items that have received FDA marketing authorization, we intended to exclude devices that lack FDA marketing authorization (87 FR 38511). In the absence of evidence that the renal dialysis equipment or supply is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date

⁵⁹ Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: <https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing>. Accessed on March 14, 2023.

⁶⁰ Food & Drug Administration. Class I and Class II Device Exemptions. Available at: <https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions>. Accessed on May 30, 2023.

of the FDA marketing authorization, the equipment or supply would not meet the TPNIES newness criterion under § 413.236(b)(2).

We received one application for the TPNIES for CY 2024. A discussion of the application is presented below.

3. CY 2024 TPNIES Application for Buzzy® Pro

Pain Care Labs™ submitted an application for the TPNIES for Buzzy® Pro for CY 2024. Buzzy® Pro is one of several models of the Buzzy® device. The Buzzy® device is intended to control pain associated with needle procedures and for temporary relief of minor injuries. Buzzy® Pro is a palm-sized external use vibration device used with unique ice packs and is intended to temporarily desensitize and physiologically block pain associated with dialysis cannulation. The applicant stated that dialysis cannulation pain affects 12 to 80 percent of dialysis patients and is a substantial contributor to reduced quality of life.^{61,62} The applicant further stated that cannulation pain is associated with fear of the cannulation process, the decision to undergo hemodialysis and sometimes the hemodialysis itself.

The applicant described the steps for using Buzzy® Pro during dialysis: (1) thread the hands free strap or regular tourniquet through the ice pack and the device so that the ice pack is on the concave side of the device; (2) attach the device and the ice directly over the site; (3) activate the vibration toggle switch and leave in place 30 to 120 seconds; (4) during cannulation, move the device proximally so the dot on the side opposite the switch is 2 to 3 cm proximal to the cannulation site; (5) clean the site per cannulation protocol; and (6) remove the device after the painful part of procedure is completed.

⁶¹ Kosmadakis G, Amara I, Costel G. Pain on arteriovenous fistula cannulation: A narrative review. *Semin Dial* 2021;34(4):275-84 doi: 10.1111/sdi.12979 [published Online First: 20210507].

⁶² Kosmadakis G, Amara B, Costel G, Lescure C. Pain associated with arteriovenous fistula cannulation: Still a problem. *Nephrol Ther* 2022;18(1):59-62 doi: 10.1016/j.nephro.2021.05.002 [published Online First: 20210618].

a. Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, pain management associated with dialysis cannulation is a service that is furnished to individuals for the treatment of ESRD and is essential for the delivery of maintenance dialysis, and therefore would be considered a renal dialysis service under § 413.171.

b. Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that it is seeking 510(k) marketing authorization from the FDA for a new utility and design of Buzzy® created for dialysis fistulae sites, patented in 2022 under the name Buzzy® Pro. To be eligible for the TPNIES, the applicant must apply within 3 years of the FDA marketing authorization date and receive FDA marketing authorization by the HCPCS Level II deadline of July 3, 2023.

The applicant submitted the indications for use portion of its FDA 510(k) application that identifies Buzzy® as all Buzzy® models: Mini Healthcare, XL Healthcare, Mini Personal, XL Personal and Pro to control pain associated with needle procedures including dialysis and the temporary relief of minor injuries. The applicant provided supplemental information in a document titled “510(k) Summary” that included a comparison table of the Predicate Device (K130631) to the Subject Device (K202993). The document indicated that only the Buzzy® Pro model is recommended for dialysis. The document also indicated that Buzzy® Pro is identical to the predicate device in terms of materials, vibration motor, circuitry, functionality, and intended use; differs only in shape but is comparable in size to the predicate device; and Buzzy® Pro is distinguished by its rectangular shape to offer users a more professional looking alternative to the bee-shape of the other device. We would be interested in better understanding the way in which the Buzzy® Pro, that is the subject of this TPNIES application, differs from the other Buzzy®

models and whether Buzzy® Pro is indicated for adult versus pediatric patients, or both. We note that to satisfy the newness criterion, the FDA 510(k) marketing authorization must have been issued within 3 years covering the specific device and model that is the subject of the TPNIES application. We welcome public comment on this issue.

c. Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that it expects Buzzy® Pro would be commercially available immediately after receiving FDA marketing authorization.

d. HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 3, 2023, the applicant stated that it intends to apply by the deadline.

e. Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(1) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant presented two substantial clinical improvement claims. First, the applicant stated that Buzzy® Pro controls needle pain for dialysis. Specifically, per the applicant, Buzzy® Pro makes cannulation pain relief available to dialysis patients, which significantly improves clinical outcomes related to depression and discontinuation of dialysis due to needle pain. Second, the applicant stated that Buzzy® Pro reduces needle fear.

With respect to the claim that Buzzy® Pro controls needle pain for dialysis, the applicant stated that currently, the most effective options for dialysis cannulation pain are the topical

anesthetic, EMLA® and vapocoolant spray.⁶³ Per the applicant, systematic reviews recommend against vapocoolant use due to lack of efficacy⁶⁴ and EMLA® incurs \$15 cost per use and takes 1 hour to become effective. The applicant asserted that the Buzzy® device has been shown to be superior to vapocoolant spray⁶⁵ and equivalent to topical anesthetics EMLA® and LMX® at a fraction of the cost and time.^{66,67} The applicant stated that while ice is effective for reducing dialysis pain for both adults and children, it is messy and inferior. The applicant further stated that a Buzzy® device cannulation study in adults found that ice is only 10 percent of the effect, with the mechanical gate control neuromodulation (vibration) providing 90 percent of the pain relief.⁶⁸

With respect to the claim that Buzzy® Pro reduces needle fear, the applicant stated that 25 to 47 percent of chronic kidney patients have needle fear.⁶⁹ The applicant further stated that the Centers for Disease Control and Prevention (CDC) recommends vibrating cold devices for needle fear in children, and cold devices with a buzzer for adults.⁷⁰ The applicant also stated that meta-analyses demonstrate significant fear reduction with Buzzy® device,⁷¹ and a New Zealand

⁶³ Çelik G, Özbek O, Yılmaz M, Duman I, Özbek S, Apiliogullari S. Vapocoolant spray vs lidocaine/prilocaine cream for reducing the pain of venipuncture in hemodialysis patients: a randomized, placebo-controlled, crossover study. *Int J Med Sci* 2011;8(7):623-7 doi: 10.7150/ijms.8.623 [published Online First: 20111012].

⁶⁴ Hogan ME, Smart S, Shah V, Taddio A. A systematic review of vapocoolants for reducing pain from venipuncture and venous cannulation in children and adults. *J Emerg Med* 2014;47(6):736-49 doi: 10.1016/j.jemermed.2014.06.028 [published Online First: 20140829].

⁶⁵ Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. *Clin J Pain* 2009;25(8):705-10 doi: 10.1097/AJP.0b013e3181af1236 [published Online First: 2009/11/19].

⁶⁶ Lescop K, Joret I, Delbos P, et al. The effectiveness of the Buzzy® device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomised, non-inferiority study. *Int J Nurs Stud* 2021;113:103803 doi: 10.1016/j.ijnurstu.2020.103803 [published Online First: 20201019].

⁶⁷ Potts DA, Davis KF, Elci OU, Fein JA. A Vibrating Cold Device to Reduce Pain in the Pediatric Emergency Department: A Randomized Clinical Trial. *Pediatr Emerg Care* 2017 doi: 10.1097/pec.0000000000001041 [published Online First: 2017/01/26].

⁶⁸ Abidin NH. Assessing The Effectiveness Of A Thermomechanical Device (Buzzy®) In Reducing Venous Cannulation Pain In Adult Patients. *Middle East Journal of Anesthesiology* 2018;25(1):61-67.

⁶⁹ Duncanson E, Le Leu RK, Shanahan L, et al. The prevalence and evidence-based management of needle fear in adults with chronic disease: A scoping review. *PLoS One* 2021;16(6):e0253048 doi: 10.1371/journal.pone.0253048 [published Online First: 20210610].

⁷⁰ Easy to Read: Needle Phobia. Available at: <https://www.cdc.gov/ncbddd/humandevlopment/covid-19/needle-phobia/index.html> Accessed March 9, 2023.

⁷¹ Ballard A, Khadra C, Adler S, Trottier ED, Le May S. Efficacy of the Buzzy® Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis. *Clin J Pain* 2019 doi: 10.1097/ajp.0000000000000690 [published Online First: 2019/03/05].

study demonstrated improved adherence to Bicillin injections with fear reduced 50 percent after three uses of Buzzy® device.⁷² The applicant also stated that Buzzy® device is indicated by Health Canada to “control pain and fear from needles” and is used for fearful dialysis patients in the Netherlands.

The applicant submitted 33 unique sources of evidence with its application in support of its claims of substantial clinical improvement. Thirty of the sources that were submitted examined the effect of external cold and vibration devices, including the Buzzy® device, though not Buzzy® Pro, during needle procedures other than dialysis cannulation. One article examined the effect of cryotherapy on pediatric pain management at the arteriovenous fistula site during hemodialysis.⁷³ Because the study did not examine the effect of external cold and vibration devices such as the Buzzy® device or more specifically the device that is the subject of this TPNIES application, Buzzy® Pro, in managing dialysis related pain or fear, it was not directly applicable to the applicant’s substantial clinical improvement claims. One article evaluated the effectiveness of distraction cards, in pediatrics in reducing pain and anxiety during intramuscular injection.⁷⁴ Because the study did not examine the effect of external cold and vibration devices such as the Buzzy® device or the Buzzy® Pro device in managing dialysis-related pain or fear, it was not directly applicable to the applicant’s substantial clinical improvement claims. One document labeled as Dutch guidelines was submitted in non-English text and thus, was not readily accessible to our review team.

The applicant also submitted a list of references, referred to as a literature review, that pertained to the applicant’s products, among which, the Buzzy® device was listed as relieving or reducing needle pain and fear and for needle procedures and for musculoskeletal pain.

⁷² Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board. *J Paediatr Child Health* 2014;50(2):112-7 doi: 10.1111/jpc.12400 [published Online First: 2013/10/19].

⁷³ Attia, A., Hassan, A. Effect of cryotherapy on pain management at the puncture site of arteriovenous fistula among children undergoing hemodialysis. *International Journal of Nursing Sciences* 2017; (4) 46-51.

⁷⁴ Sahiner, N., Turkmen, A. The Effect of Distraction Cards on Reducing Pain and Anxiety During Intramuscular Injection in Children. *Worldviews on Evidence-Based Nursing* 2019; 1-6.

In a document titled “Summary of Clinical Evidence – relief of needle pain and fear,” the applicant presented the study objectives and key features of 29⁷⁵ of the 30 submitted sources that examined the effect of external cold and vibration devices, including the Buzzy® device, though not Buzzy® Pro, during needle procedures other than dialysis cannulation. The document identified several additional sources that were not submitted by the applicant. Finally, the applicant submitted a document titled “Buzzy Fear reduction rationale and table” that duplicated information already captured in the “Summary of Clinical Evidence – relief of needle pain and fear” document. Table 10 below lists the 29 sources that were both identified by the applicant in the “Summary of Clinical Evidence – relief of needle pain and fear” document and that were submitted. We have not included sources that were mentioned by the applicant, but not submitted to us.

TABLE 10: Applicant’s Substantial Clinical Improvement Sources

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
(1) O: Pain relief and anxiety reduction for pediatric needle procedures F: Systematic review and meta-analysis N=1138 P: 3 – 18 y/o	Buzzy	(1) Self-Reported pain reduction - 1.11; 95% [CI]: -1.52 to -0.70; P<0.0001) Of 4 studies only assessing lab draws, IV catheter/venipuncture procedures (SMD: -1.30; 95% CI: -1.84 to -0.76 P<0.00001)	Ballard A Khadra C, Adler S, Doyon- Trottier E, Le May S. <i>Efficacy of the Buzzy Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis.</i> Clin J Pain. 2019 June; 35(6):532-543.
(2) O: Anxiety reduction F: Systematic Review and Meta-analysis N=1138 P: 2-17y		(2) (Pain reduction -1.11; 95% confidence interval [CI]: -1.52 to -0.70; P<0.0001), anxiety reduction (SMD -1.37; 95% CI: -1.77 to -0.96; P<0.00001)	
O: Pain relief and anxiety reduction for pediatric needle procedures F: Systematic review and meta-analysis N=1479 P: 2 – 18 y/o	Multiple devices	Meta-regression demonstrated a significant negative correlation of pain score with age. For children at 8.5 years, cold vibration reduced the pain score by 0.13 averagely for every increment in year compared with controls (MD -0.13; 95% CI: -0.25, -0.01)	Su HC, Hsieh CW, Lai NM, Chou PY, Lin PH, Chen KH. <i>Using vibrating and cold device for pain relievers in children: a systematic review and meta-analysis of randomized controlled trials.</i> J Pediatr Nurs. 2021 Mar 15; 61:23-33.

⁷⁵ The following source was not included in the summary table: Redfern RE, Chen JT, Sibrel S, Effects of Thermomechanical Stimulation during Vaccination on Anxiety, Pain, and Satisfaction in Pediatric Patients: A Randomized Controlled Trial. J Pediatr Nurs.2018.38: 1-7.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Pain relief for cannulation in pediatrics F: RCT: Buzzy compared to LMX topical anesthetic N=173 P: 18 months – 17 y/o	Buzzy M-stim only	There were no statistically significant differences among treatment groups based on the observational measures of pain or the self-report measures of pain. Findings support the use of both mechanical vibration and topical anesthetic as effective in children regardless of age group or sex.	Bahorski JS, Hauber RP, Hanks C, Johnson M, Mundy K, Ranner D, Stoutamire B, Gordon G. <i>Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study.</i> Int J Nurs Stud. 2015 Oct;52(10):1553-64.
O: Pain relief and first stick vascular access success in pediatric emergency F: RCT: Buzzy v. Vapocoolant N=81 P: 4 – 18 y/o	Buzzy	Vascular access success more likely w/ Buzzy: (odds ratio, 3.05; 95% CI, 1.03- 9.02), p=.040); Self-reported pain scores lower with Buzzy: (-2; 95% CI, -4 to 0) than with vapocoolant (p=.029). Parent reported pain scores lower with Buzzy (-2; 95% CI -4 to -2) than vapocoolant (p=.005).	Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. <i>An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department.</i> Pediatr Emerg Care. 2011 Dec;27(12):1151-6.
(1) O: Pain relief in adult vascular access F: RCT: Buzzy v. Vapocoolant N=31 P: 18+ Years Hospital employees (2) O: Pain relief with cannulation on the dorsum of hand F: Crossover trial rated with VAS N=31 P: Adult healthcare workers	Buzzy	(1) In a crossover trial, Buzzy reduced angiocath placement pain (mean 9.9 mm, 95% [CI] 0.82-19, P=0.035, SD 16) compared to vapocoolant (mean 7.9 mm, 95% [CI]-1.8-17.7, P=0.1, SD 16.9) (2) Each 20mm of pre-procedural fear increased the likelihood of a successful intervention pain relief (odds ratio 2, P=0.043).	Baxter AL, Leong T, Mathew B. <i>External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device.</i> Clin J Pain. 2009 Oct;25(8):705-10.
(1) O: Pain and anxiety relief in vascular access procedures in children F: RCT: Buzzy, Buzzy + Cartoons, Cartoons alone, Control/nothing. N=150 P: Mean age 9.4 years (2) O: Fear reduction using Buzzy v. Cartoons v. Nothing v. Buzzy + Cartoons F: RCT N=150 P: Pediatric 5-12 years	Buzzy	(1) Pain: “Buzzy was highly effective in children younger than 9 (p=0.04). Also, a significant efficacy was recorded in the Buzzy and Cartoon group (p=0.04) for the nurse's perception of the child's pain, and in the Buzzy group for the mother's perception of the child's pain (p=0.002).” Anxiety: “Particularly, the difference was statistically significant in the Buzzy (p=0.03) and the Buzzy and animated Cartoon groups (p=0.02) for nurses' perception of the child's anxiety, and in the Buzzy group for mothers' perception of anxiety (p=0.03).” (2) (Children’s Emotional Manifestation Scale for anxiety: per nursing and mother evaluation) Nothing -0.26 v. Buzzy -0.86 P=.03. Nothing -0.26 v. Buzzy + Cartoons -0.89 P=.02 Nothing -0.26 v. Cartoons alone - .073 P=.09).	Bergomi P, Scudeller L, Pintaldi S, Dal Molin A. <i>Efficacy of Non-pharmacological methods of pain management in children undergoing venipuncture in a pediatric outpatient clinic: A randomized controlled trial of audio-visual distraction and External Cold and Vibration.</i> J Pediatr Nurs. 2018 Sep-Oct; 42: e66-e72.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Pain reduction comparison in children during vascular access F: RCT: Buzzy, Bubbles, and Control N=96 P: 3 – 6 y/o	Buzzy	Pain scores were lower in the groups of Buzzy and blowing soap bubbles than the control group. There was no statistical difference between Self Report, Parent Report, Nurse Report, or Researcher Report between Buzzy and Bubbles. The differences between Buzzy or Bubbles and Control was significant for all $P=.0000$.	Binay Ş, Bilsin E, Gerçeker GÖ, Kahraman A, Bal-Yılmaz H. <i>Comparison of the Effectiveness of Two Different Methods of Decreasing Pain During Phlebotomy in Children: A Randomized Controlled Trial</i> . J Perianesth Nurs. 2019 Feb 20 S1089-9472(18)30414-3.
O: Superiority trial of pain relief during vascular access F: RCT: Buzzy, Handheld computer distraction N=200 P: 4-12 y/o	Buzzy	No significant difference between a handheld computer distraction and Buzzy, median (IQR) = 3.0 (1.0–4.8) and 2.0 (1.0–4.8), respectively, $P = 0.72$.	Cozzi G, Crevatin F, Dri V, Bertossa G, Rizzitelli P, Matassi D, Minute M, Ronfani L, Barbi E. <i>Distraction Using Buzzy or Handheld Computers During Venipuncture</i> . Pediatr Emerg Care. 2018 Dec 27.
O: Pain relief during pediatric vascular access F: RCT: Virtual Reality (VR) versus Buzzy N=121 P: 7 - 12 y/o	Buzzy	Buzzy resulted in lower pain than VR and significantly better than control, $P = .000$). Buzzy $n=40$; $1.5 \pm .2SD$ versus VR $n=41$; $2 \pm .2SD$, $p<.0001$).	Gerçeker GÖ, Binay Ş, Bilsin E, Kahraman A, Yılmaz HB. <i>Effects of Virtual Reality and External Cold and Vibration on Pain in 7- to 12-year- old Children During Phlebotomy: A Randomized Controlled trial</i> . J Perianesth Nurs. 2018 Mar 17.
O: Pain Relief for vascular access with Buzzy, Buzzy + Distraction, Distraction, and Control F: RCT: 4 arm trial N=218 P: 6 - 12 y/o	Buzzy	All groups using Buzzy had significantly reduced pain ($P < 0.001$) compared to the control group. Lowest pain measured w/Buzzy in combination w/DistrAction Cards.	Inal S., Kelleci M. <i>The Effect of External Thermomechanical Stimulation and Distraction on Reducing Pain Experienced by Children During Blood Drawing</i> . Pediatr Emerg Care. 2020 Feb;36(2):66-69.
(1) O: Pain relief during vascular access in pediatric patients F: RCT: [Buzzy v. control] N=120 P: 6 - 12 y/o (2) O: Pain and anxiety relief with lab draws F: RCT using Child Pain Scale N=120 P: 6-12y/o	Buzzy	(1) Lower pain ($p < .001$) and anxiety ($p < .001$ w/ Buzzy) compared to the control group. (2) (Lower pain ($p < .001$) and anxiety with Buzzy. CAPS Parent reported 1.61(Buzzy) v. 3.36 (Control) ($p < .001$))	Inal S, Kelleci M. <i>Relief of pain during blood specimen collection in pediatric patients</i> . MCN Am J Matern Child Nurs. 2012 Sep;37(5):339-45. PMID: 22895207.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
<p>(1) O: Pain, stress cortisol level, and fear relief during vascular access comparing Buzzy, Jet Lidocaine, Bubbles and aromatherapy F: RCT N=195, 39 x 5 groups P: 5 – 10 y/o</p> <p>(2) O: Pain, stress cortisol level, and fear relief during vascular access comparing Buzzy, Jet Lidocaine, Bubbles and aromatherapy F: RCT N=195, 39 x 5 groups P: 5 – 10 y/o</p>	Buzzy	<p>“A significant difference was found between the intervention and control groups in terms of levels of pain during and after phlebotomy in favor of the Buzzy group ($p<0.05$).”</p> <p>(2) (“children in the Buzzy group were less frightened during phlebotomy (CFS 1.33 v. 2.66 $p < 0.05$).” “There was a significant difference between intervention and control groups fear levels in favor of the Buzzy group during phlebotomy ($p < 0.05$).”</p>	Küçük Alemdar D, Yaman Aktaş Y. <i>The use of the Buzzy, Jet lidocaine, bubble-blowing and aromatherapy for reducing pediatric pain, stress and fear associated with phlebotomy.</i> J Pediatr Nurs. 2019 Jan 30 S0882-5963(18)30352- X.
<p>O: Pain and anxiety in adults during cannulation using Buzzy or control. F: RCT N=100 P: Mean age: 49.6 +/- 13.8y</p>	Buzzy	<p>Pain was less than expected in 44/50 Buzzy patients and 0/50 control, and more than expected in no Buzzy patients and 6/50 control ($P<.000$), with overall less pain (1.04 v 5.32) and greater satisfaction. (95.3 v 2.12) $P<.001$. There was no difference in pulse, state, or trait anxiety before or after cannulation.</p>	Pakış Çetin S, Çevik K. <i>Effects of Vibration and Cold Application on Pain and Anxiety During Intravenous Catheterization.</i> J Perianesth Nurs. 2019 Aug;34(4):701-709.
<p>O: Pain relief during vascular access in children with cognitive impairment F: RCT: Buzzy v. Control N=70 P: Median age – 9 y/o</p>	Buzzy	<p>“Reported no or mild procedural pain in 32 cases (91.4%) in the Buzzy group and in 22 cases (61.1%) in the no-intervention group ($p = 0.003$).”</p>	Schreiber S, Cozzi G, Rutigliano R, Assandro P, Tubaro M, Cortellazzo Wiel L, Ronfani L, Barbi E. <i>Analgesia by cooling vibration during venipuncture in children with cognitive difficulties.</i> Acta Paediatr. 2016 Jan;105(1): e12-6.
<p>O: Efficacy of Buzzy for pain reduction in children F: RCT N=72 P: 3 – 10 y/o</p>	Buzzy	<p>Buzzy pain 3.65 vs Magic Glove 4.67 ($p=.039$).</p>	Susam V, Friedel M, Basile P, Ferri P, Bonetti L. <i>Efficacy of the Buzzy System for pain relief during venipuncture in children: a randomized controlled trial.</i> Acta Biomed. 2018 Jul 18;89(6-S):6-16.
<p>(1) O: Effect of Buzzy, distraction cards, and balloons in reducing pain and anxiety in children receiving procedure requiring vascular access F: RCT N=180 P: 7 – 12 y/o</p> <p>(2) O: Fear reduction with venipuncture F: RCT with CFS N=180 P: pediatrics 9.3 +/- 1.9 years</p>	Buzzy	<p>(1) Lowest pain scores with Buzzy (1.90 ± 1.34) vs Distracting cards (3.17 ± 2.13) vs Balloon inflating (2.83 ± 1.41) vs control (4.15 ± 1.29), ($p=0.012$)</p> <p>(2) (Fear with Children’s Fear Scale lowest with Buzzy (0.61) versus control (3.17), one way ANOVA with 4 arms $p=.13$ “clinically significant rather than statistically significant.” – $p <.0001$ if Buzzy compared to control, $p=.003$ if compared to Balloon inflating (CFS 1.19).</p>	Tork HM <i>Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department.</i> Am J Nursing Science 2017 Feb;6(2):26- 32.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Effect of vibration on outpatient vascular access in children F: Retrospective review N=64 P: 4 – 18 y/o	Buzzy	“21 of the 26 [phlebotomists’] (80.8%) responses provided indicated that the device made the procedure easier; the other 5 claimed that it had no effect.”	Whelan HM, Kunselman AR, Thomas NJ, Moore J, Tamburro RF. <i>The impact of a locally applied vibrating device on outpatient venipuncture in children</i> . Clin Pediatr (Phila). 2014Oct;53(12):1189-95.
(1) O: Effect of vibration in reducing needle pain in children F: Systematic review N= 264 P: 0 - 18 y/o (2) O: Identify, evaluate and synthesize evidence of the effectiveness of vibratory stimulation to reduce needle-related procedural pain in children aged 18 years and younger. F: Systematic Review N=n/a P: 0 – 18 y/o	Buzzy	(1) “The effect size for the Buzzy tended to be higher than that for the other devices.” “Buzzy self-rated pain (n=): -0.94, [95% CI]: -1.54, -0.35) p<.00001. [With Buzzy] the effect on the child's anxiety (SMD: -1.03, 95% CI: -1.85 to -0.20 p<.00001) was significant.” (2) Comparison devices DentalVibe and Vibrational Anesthesia Device used primarily or exclusively for Dental procedures. “The effect size for the Buzzy tended to be higher than that for the other devices. Overall, vibratory stimulation was significantly effective: self-rated pain: -0.55, 95% confidence interval [95% CI]: -0.92 to -0.18) observer-rated pain outcomes (SMD: -0.47, 95% CI: -0.76 to -0.18).”	Ueki S, Yamagami Y, Makimoto K. <i>Effectiveness of vibratory stimulation on needle-related procedural pain in children: a systematic review</i> . JBI Database System Rev Implement Rep. 2019 Jul;17(7):1428-1463.
O: Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors F: Abstract N=90 P: Adult men	Buzzy	“Results indicate that the use of the Buzzy device was an effective method of reducing the pain of phlebotomy and increasing phlebotomy satisfaction in healthy adult male blood donors.” [N=90, Pain 20.93 +/- 15.1 versus 35.23 +/- 19.3, p=.004, satisfaction Buzzy 76.0 +/- 23.7 v. 55.26 +/- 34.8 control, (p=.031)].	Yilmaz D., Heper Y., Gözler. <i>Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors</i> . Pain Management Nursing. 2017 Aug;18(4):260-267. PMID: 28601479.
(1) O: Pain relief during intraoral injections using FLACC F: RCT N=50 P: 5-10 y/o (2) O: Oral dental injections F: RCT FLACC N=50 P: 5-10 years	Buzzy	(1) Conclusion: “Buzzy® can reduce pain and anxiety during local anesthetic delivery for various dental procedures”. 1.4 Buzzy, 3.96 Conventional using FLACC, p<.05 (2) “Buzzy® can reduce pain and anxiety during local anesthetic delivery for various dental procedures.” FLACC 1.4 Buzzy, 3.96 Conventional, p<.05	Suohu T, Sharma S, Marwah N, et al. A Comparative Evaluation of Pain Perception and Comfort of a Patient Using Conventional Syringe and Buzzy System. Int J Clin Pediatr Dent 2020;13(1):27-30.
O: Pain and anxiety relief for cannulation F: RCT VAS anxiety VAS pain N=176 P: 7-12 y/o	Buzzy	(WBFS pain Buzzy 2.75, Control 5.7 p=0.000, VAS pain Buzzy 1.66, Control 4.09 p=.000; VAS anxiety Buzzy 0.94, Control 2.09 p=.000; VAS observer anxiety Buzzy 0.92, Control 2.14 p=.000.).	Canbulat N, Ayhan F, Inal S. <i>Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients</i> . Pain Manag Nurs. 2015 Feb;16(1):33-9.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Pain and anxiety relief for vascular access with Child Fear Score F: RCT Virtual Reality v. Distraction cards v. Buzzy v control N=142 P: 7-12 y/o	Buzzy	“According to all raters, the Buzzy® group had the lowest mean CFS score, followed by the VR, DC, and control groups ($p < 0.05$).”	Erdogan B, Ozdemir AA. <i>The Effect of Three Different Methods on Venipuncture Pain and Anxiety in Children: Distraction Cards, Virtual Reality and Buzzy (Randomized Controlled Trial)</i> . J Pediatr Nurs. May-Jun 2021;58:e54-e62.
O: Pain, fear and anxiety from vaccination F: Systematic Review 27 articles N=n/a P: 4 – 15 years	Buzzy	“This review found consistent evidence for reduction in pain, distress and/or fear with interventions that combined cooling and vibrating together...” [pooled data not reported].	Lee VY, Caillaud C, Fong J, Edwards KM. <i>Improving vaccine-related pain, distress or fear in healthy children and adolescents-a systematic search of patient-focused interventions</i> . Hum Vaccin Immunother. 2018;14(11):2737-2747.
O: Anxiety and pain reduction with cannulation F: RCT Buzzy v control N=105 P: Elective Surgical Adults	Buzzy	(In subjects who reported higher pre procedure anxiety, the experimental [Buzzy] group reported lower pain (0.84 ± 0.50) than the control group (3.92 ± 0.58).	Redfern RE, Micham J, Sievert D, Chen JT. <i>Effects of Thermomechanical Stimulation During Intravenous Catheter Insertion in Adults: A Prospective Randomized Study</i> . J Infus Nurs. 2018 Sept/Oct;41(5):294-300.
O: Pain relief with flu vaccination F: RCT VAS, 10-point satisfaction scale N=497 P: Adult employees influenza vaccine clinic	Buzzy	(pain 0.87 v 1.12 $p=.035$, better than previous experiences 62% Buzzy 23.9% control $p<.0001$.) “Buzzy can be used in adult patients to reduce pain during immunization and is especially effective in those with high levels of anxiety.”	Redfern RE, Micham J, Seegert S, Chen JT. <i>Influencing Vaccinations: A Buzzy Approach to Ease the Discomfort of a Needle Stick – a prospective, Randomized Controlled Trial</i> . Pain Management Nursing, 2019 Apr;20(2):164-169.
O: Reduction in fear and pain with Bicillin injections F: Observational prospective interventional trial N=118 P: Teens and Adults	Buzzy	(Nonadherent group offered Buzzy, LA bicillin, or both; overall pain and fear reduced 50%, Special needle phobia clinic able to be disbanded.)	Russell K, Nicholson R, Naidu R. <i>Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board</i> . J Paediatr Child Health. 2014 Feb;50(2):112-7.
O: To investigate the effect of the Buzzy application on pain and satisfaction during injections. F: RCT N=65 P: Average age 52	Buzzy	(Pain 74% reduced, satisfaction 95 v. 84. $P<.001$ both favor Buzzy).	Sahin M. <i>Effect of Buzzy® application on pain and injection satisfaction in adult patients receiving intramuscular injections</i> . Pain Management Nurs 2018 Dec;19(6):645.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Immunization pain and fear reduction Buzzy v. control with TdAP F: RCT Children Fear Scale N=104 P: 7-year-olds	Buzzy	Buzzy: 0.58 +/- 0.63 v. 1.96 +/- 1.13 p=.001 Finding: The experimental group showed significantly lower pain and anxiety levels than the control group during immunization. Conclusions/implications for practice: The combined stimulation of skin with external cold and vibration can be used to reduce pain and anxiety during pediatric immunization.	Sahiner NC, Inal S, Akbay AS. <i>The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children.</i> J Perianesth Nurs. 2015 Jun;30(3):228-35.
O: Buzzy Bubbles Shotblocker or nothing for IM injections F: RCT 4 arm N=160 P: 5-10 years	Buzzy	Results: A significant difference was found between the intervention and control groups in terms of levels of pain and fear during IM injection. Pain and fear were notably less in the group of children receiving the Buzzy intervention. Discussion: The Buzzy intervention should be used when children are undergoing IM injections to reduce their levels of pain and fear.	Yilmaz G, Almdar DK. <i>Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear Caused by Intramuscular Injection: A Randomized Controlled Trial.</i> J Emerg Nurs. 2019 Sep;45(5):502-511.

(2) CMS Preliminary Assessment of Substantial Clinical Improvement Claims and Sources

We summarize our specific concerns regarding the substantial clinical improvement criteria under §§ 413.236(b)(5) and 412.87(b)(1) in the paragraphs that follow. We note that, consistent with § 413.236(c), CMS will announce its final determination regarding whether the Buzzy® Pro meets the substantial clinical improvement criteria and other eligibility criteria for the TPNIES in the CY 2024 ESRD PPS final rule.

As stated previously, the applicant must demonstrate that the equipment or supply meets at least one of the following three substantial clinical improvement criteria in order to be eligible for the TPNIES: (1) the item offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment; (2) the item offers the ability to diagnose a medical condition in the patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods; or (3) the item significantly improves clinical

outcomes relative to services or technologies previously available. The applicant stated that Buzzy® Pro makes dialysis cannulation pain relief available to dialysis patients, which significantly improves clinical outcomes related to depression and discontinuation of dialysis due to needle pain. Therefore, we believe that the applicant is targeting the clinical outcomes criterion (number (3) above). The applicant also stated that Buzzy® Pro reduces needle fear. We did not identify evidence within the application or the submitted materials documenting improved clinical outcomes related to depression or dialysis adherence but would be interested in reviewing such evidence.

With respect to the submitted evidence, it does not appear that the studies reflect the use of (1) Buzzy® Pro, the device that is the subject of the TPNIES application, nor (2) Buzzy® Pro in the context of dialysis cannulation. Specifically, the applicant submitted an application for Buzzy® Pro, indicating that Buzzy® Pro is a new design created for dialysis fistulae sites, patented in 2022. However, the sources submitted were dated prior to the 2022 new design patent date for dialysis fistulae sites. As such, it appears that the sources submitted reflect the use of a predecessor Buzzy® device. In addition, while the applicant's "Summary of Clinical Evidence" document presented sources as evaluating Buzzy® Pro's efficacy in managing vascular access pain or fear, we note that none of these sources appear to evaluate vascular access in the context of dialysis cannulation. The studies evaluated pain and fear in the context of other types of needle procedures, including vaccine or medication injections, blood specimen collection, and intravenous catheter insertion.

It is unclear whether findings of pain or fear reduction from the use of the Buzzy® device in non-dialysis needle procedures could be extrapolated to dialysis cannulation pain or fear. There are several unique features to dialysis cannulation that may limit generalizability. These include the need for regular punctures several times per week, the maintenance of cannulation for several hours during dialysis treatments, the use of substantially larger needle sizes in dialysis, and complications that are associated with frequent vascular access cannulation, such as

infections and thrombosis. As such, we question whether outcomes could reasonably be extrapolated as applicable to patients undergoing dialysis cannulation.

As identified in the table, the majority of the studies provided in support of the applicant's claims reflect pediatric patient experiences. We note that pediatric patients comprise a small proportion, just 0.14 percent, of the total Medicare ESRD patient population (87 FR 67222). As such, the data that is heavily weighted towards the pediatric population may have limited generalizability to the non-pediatric majority of the ESRD patient population.

While the applicant stated that the Buzzy® devices are less expensive than topical anesthetic, we note that cost is not an eligibility criterion for the TPNIES.

It is also unclear whether a single Buzzy® Pro device and its components (for example, tourniquet and ice pack) are intended for single versus multiple patient use in the ESRD facility setting. To the extent that the device or its components are intended for use among multiple patients, we would be interested in data that examines the risk of infection associated with the use of Buzzy® Pro in the dialysis patient population. Additionally, we are not aware of any data that examines the risk of harm to the dialysis access site or any other adverse events associated with use of the Buzzy® Pro in the dialysis patient population, including access and bloodstream infections and thromboses but would be interested in the results of such data.

In addition, the applicant stated that currently, the most effective options for dialysis cannulation pain are topical anesthetics and vapocoolant spray. We would be interested in studies comparing the use of Buzzy® Pro to topical anesthetics or vapocoolant and that demonstrate that Buzzy® Pro significantly improves clinical outcomes of dialysis patients relative to existing available treatments.

We are inviting public comments on whether the Buzzy® Pro meets the substantial clinical improvement criteria for the TPNIES.

f. Capital-Related Assets Criterion (§ 413.236(b)(6))

With respect to the sixth TPNIES eligibility criterion under § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, we note that Buzzy® Pro does not meet the definition of a capital-related asset under § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership that is subject to depreciation.⁷⁶

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2024

In this section of the proposed rule, we identify any items previously approved for the TPNIES and for which payment is continuing for CY 2024. As described in the CY 2023 ESRD PPS final rule, payment for the one item approved for TPNIES, the Tablo® Hemodialysis System, as described by HCPCS code E1629, expires on December, 31, 2023 (87 FR 67216). As such there are no items previously approved for TPNIES for which payment is continuing in CY 2024.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2024

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In December 2021, CMS approved *Korsuva*TM (difelikefalin) for the TDAPA under the ESRD PPS, effective April 1, 2022. Implementation instructions are specified in CMS Transmittal 11295,⁷⁷ dated March 15, 2022, and available at: <https://www.cms.gov/files/document/r11295CP.pdf>. In this section of the proposed rule, we provide a table that identifies the one new renal dialysis drug that was approved for the TDAPA effective in CY 2022, and for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2024. Table 11 also identifies the product's HCPCS coding information as well as the payment adjustment effective date and end date.

⁷⁶ See also CMS Provider Reimbursement Manual, Chapter 1, section 104.1. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>

⁷⁷ CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022.

TABLE 11: Continuation of Approved Transitional Drug Add-On Payment Adjustments

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0879	Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)	4/1/2022	3/31/2024

III. Calendar Year (CY) 2024 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114-27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in

§ 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Proposed Annual Payment Rate Update for CY 2024

1. CY 2024 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.1.d of this proposed rule, the proposed ESRD PPS base rate is \$269.99, which reflects the application of the proposed CY 2024 wage index budget-neutrality adjustment factor of 0.999652 and the proposed CY 2024 ESRDB market basket percentage increase of 2.0 percent reduced by the proposed productivity adjustment of 0.3 percentage point, that is, 1.7 percent. Accordingly, we are proposing a CY 2024 per treatment payment rate of \$269.99 ($(\$265.57 \times 0.999652) \times 1.017 = \269.99) for renal dialysis services furnished by ESRD facilities to individuals with AKI. This proposed payment rate is further adjusted by the wage index, as discussed in the next section of this proposed rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.1.b

of this proposed rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We also apply the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. As stated previously, we are proposing a CY 2024 AKI dialysis payment rate of \$269.99, adjusted by the ESRD facility's wage index.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to previous ESRD QIP rules at: 75 FR 49030; 76 FR 628; 76 FR 70228; 77 FR 67450; 78 FR 72156; 79 FR 66120; 80 FR 68968; 81 FR 77834; 82 FR 50738; 83 FR 56922; 84 FR 60648; 85 FR 71398; 86 FR 61874; and 87 FR 67136.

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Proposals to Update the Regulation Text for the ESRD QIP

1. Proposal to Revise the Definition of "Minimum Total Performance Score (mTPS)" at § 413.178(a)(8)

In the CY 2019 ESRD PPS final rule, we codified a number of key terms used in the ESRD QIP at § 413.178(a) of our regulations (83 FR 56980 through 56982). One of these terms is "minimum total performance score" (mTPS), which we defined at § 413.178(a)(8) "with

respect to a payment year”⁷⁸ as “the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.”

We have recently reevaluated this definition and determined that it should be revised to more accurately capture how we calculate the median of national ESRD facility performance on reporting measures. Although we use data prior to the performance period to calculate these medians, the data may not be from the same time period, or “baseline period” (see § 413.178(a)(2)) used to calculate the 50th percentile of national ESRD facility performance on the clinical measures. Instead, our policy has been to calculate the median of national ESRD facility performance on the ESRD QIP reporting measures using the most recently available data prior to the applicable performance period for the payment year. If there were no data available prior to the first performance period of a new reporting measure, as was the case for the Clinical Depression Screening and Follow-Up reporting measure, we would use a proxy median for purposes of including the reporting measure in our calculation of the mTPS. We selected the values for these proxy medians based on the availability of previous measure data, a facility’s familiarity with similar measures or requirements, and considerations regarding a facility’s ability to comply with new reporting measure requirements during the initial performance periods for a new reporting measure.

We are proposing to update the definition of “minimum total performance score” at § 413.178(a)(8) so that it accurately captures these policies. We are also proposing that, with respect to the adoption of future reporting measures, including the reporting measures proposed in this proposed rule, if there are an insufficient quantity of data available prior to the first performance period of a new reporting measure, we will set a proxy median of zero for the reporting measure until we have sufficient data to calculate the median. We believe that this

⁷⁸ In the CY 2023 ESRD PPS final rule, we revised § 413.178(a)(8) to exempt PY 2023 (87 FR 67229).

proposal will provide facilities with additional predictability and transparency regarding our calculation of the mTPS for a payment year. Although many facilities score much higher than zero during the initial performance periods of a new reporting measure, we believe that setting the proxy median at zero where we do not have sufficient data available will account for the possibility that new reporting measures may have different reporting requirements. For example, a new reporting measure may require a facility to report new or additional data in EQRS in order to be eligible for scoring on the reporting measure. Additionally, a new reporting measure may require that a facility reconsider its internal processes to comply with the reporting requirements and be eligible for scoring. We believe that using a median of 0 for new reporting measures would ensure that the mTPS is calculated based on the worst-case scenario, rather than assuming a median higher than what may be observed once data are available. Setting the proxy median at zero until we have sufficient data available to calculate the median would allow the timely inclusion of a new reporting measure in the ESRD QIP measure set, as well as our calculation of the mTPS, while also encouraging facilities to report the new or additional data that may be specified by that reporting measure so that they are able to receive credit for reporting.

We welcome public comment on this proposal.

2. Proposal to Codify the ESRD QIP Measure Adoption, Retention, and Removal Policies

In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the CY 2019 ESRD PPS final rule (83 FR 56983 through 56985), we finalized eight measure removal factors for the ESRD QIP, and we refer readers to that final rule for details. We also finalized a policy to retain a measure for certain specified reasons, such as when a particular measure addresses a gap in quality so significant that removing the measure could result in poor quality or when a measure addresses a statutorily-required topic, even if one or more of the measure removal factors applies. In the CY 2013 ESRD PPS final rule (77 FR 67475), we also finalized that we would generally remove an ESRD QIP measure using

notice and comment rulemaking unless we determined that the continued collection of data on the measure raised patient safety concerns. In that case, we stated that we would promptly remove the measure, immediately notify ESRD facilities and the public through the usual communication channels (including listening sessions, memos, email notification, and website postings), and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle.

We are proposing to revise 42 CFR 413.178(c) to incorporate these measure adoption, retention, and removal policies. Existing § 413.178(c)(1) through (5) would be consolidated and renumbered as § 413.178(c)(1)(i) through (v), and we would add a new § 413.178(c)(1)(vi), which would codify our policy to adopt measures for the ESRD QIP beyond those that address the topics described at § 413.178(c)(1)(i) through (v). We are also proposing to codify at § 413.178(c)(2) our policies regarding the use of endorsed measures. We are proposing to codify at § 413.178(c)(3) our policy regarding the updating of measure specifications. Additionally, we are proposing to codify at § 413.178(c)(4) our policy regarding measure retention. Finally, we are proposing to codify at § 413.178(c)(5) our policies regarding measure removal. We believe these proposals will make it easier for interested parties to find these policies and will further align the ESRD QIP regulations with the regulations we have codified for other quality reporting programs.

We welcome public comment on these proposals.

C. Proposed Updates to Requirements Beginning with the PY 2026 ESRD QIP

1. PY 2026 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). In this proposed rule, we are proposing to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure beginning with PY 2026. We are also proposing to add the Facility

Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026. Table 12 below summarizes the previously finalized and proposed new measures that we would include in the PY 2026 ESRD QIP measure set. The technical specifications for each of these measures that would apply for PY 2026 can be found in the CMS ESRD Measures Manual for the 2023 Performance Period.⁷⁹

TABLE 12: Previously Finalized and Proposed New Measures for the PY 2026 ESRD QIP Measure Set

Consensus-Based Entity⁸⁰ (CBE) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure* Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure**

⁷⁹ <https://www.cms.gov/files/document/esrd-measures-manual-v80.pdf>.

⁸⁰ In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

Consensus-Based Entity ⁸⁰ (CBE) #	Measure Title and Description
	Percentage of HCP who receive a complete COVID-19 vaccination course.
N/A	Facility Commitment to Health Equity, a reporting measure*** Facilities will receive one point each for attesting to five different domains of commitment to advancing health equity for a total of five points.

*We are proposing to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

**We are proposing to update the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2026, as discussed in section IV.C.3 of this proposed rule.

*** We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

2. Proposal to Adopt the Facility Commitment to Health Equity Reporting Measure Beginning with the PY 2026 ESRD QIP

a. Background

Significant and persistent disparities in healthcare outcomes exist in the U.S. For example, belonging to a racial or ethnic minority group, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, being a member of a religious minority, living in a rural area, being a person with a disability or disabilities, or being near or below the

poverty level, is often associated with worse health outcomes.^{81,82,83,84,85,86,87,88,89,90} Numerous studies have shown that among Medicare beneficiaries, individuals who are racial and ethnic minorities often receive lower quality hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.^{91,92,93,94,95,96} Readmission rates in the Hospital Readmissions Reduction Program have shown to be higher among Black and Hispanic Medicare beneficiaries with common conditions, including

⁸¹ Joynt KE, Orav E, Jha AK. 2011. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA*, 305(7), 675-681. Available at: doi:10.1001/jama.2011.123.

⁸² Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income Inequality and thirty-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *BMJ*, 346. Available at: <https://doi.org/10.1136/bmj.f521>.

⁸³ Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. *N Engl J Med*, 371(24), 2298-2308. Available at: doi: 10.1056/NEJMs1405003.

⁸⁴ Polyakova, M, Udalova V, Kocks, G, Genadek K, Finlay K, Finkelstein AN. 2021. Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. *Health Affairs*, 40(2), 307-316. Available at: <https://doi.org/10.1377/hlthaff.2020.02142>.

⁸⁵ Rural Health Research Gateway. 2018. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: <https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf>.

⁸⁶ HHS Office of Minority Health. 2020. Progress Report to Congress, 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Department of Health and Human Services. Available at: https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.

⁸⁷ Heslin KC, Hall JE. 2021. Sexual Orientation Disparities in Risk Factors for Adverse COVID-19–Related Outcomes, by Race/Ethnicity — Behavioral Risk Factor Surveillance System, United States, 2017–2019. *MMWR Morb Mortal Wkly Rep*, 70(5), 149. doi: 10.15585/mmwr.mm7005a1.

⁸⁸ Poteat TC, Reisner SL, Miller M, Wirtz AL. 2020. COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv. doi: 10.1101/2020.07.21.20159327.

⁸⁹ Vu M, Azmat A, Radejko T, Padela AI. 2016. Predictors of Delayed Healthcare Seeking Among American Muslim Women. *Journal of Women's Health*, 25(6), 586-593. doi: 10.1089/jwh.2015.5517

⁹⁰ Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016). The Association Between Discrimination and the Health of Sikh Asian Indians. *Health Psychology*, 35(4), 351–355. <https://doi.org/10.1037/hea0000268>

⁹¹ CMS Office of Minority Health. 2020. Racial, Ethnic, and Gender Disparities in Healthcare in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: .

⁹² CMS Office of Minority Health. Updated August 2018. Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.

⁹³ Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. 2014. Racial Disparities in Knee and Hip Total Joint Arthroplasty: An 18-year analysis of national Medicare data. *Ann Rheum Dis*, 73(12), 2107-15. Available at: doi:10.1136/annrheumdis-2013-203494.

⁹⁴ Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. 2019. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. *J Am Geriatr Soc*, 67(8), 1672-1679. Available at: <https://doi.org/10.1111/jgs.15960>.

⁹⁵ Joynt KE, Orav E, Jha AK. 2011. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA*, 305(7), 675-681. Available at: doi:10.1001/jama.2011.123.

⁹⁶ Tsai TC, Orav EJ, Joynt KE. 2014. Disparities in Surgical 30-day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *Ann Surg*, 259(6), 1086-1090. Available at: doi: 10.1097/SLA.0000000000000326.

congestive heart failure and acute myocardial infarction.^{97,98,99,100,101} Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower quality healthcare.¹⁰² Evidence of differences in quality of care received by people from racial and ethnic minority groups show worse health outcomes, including a higher incidence of diabetes complications such as retinopathy.¹⁰³ Additionally, inequities in the drivers of health affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.¹⁰⁴

In the CY 2022 ESRD PPS proposed rule (86 FR 36362 through 36369), we requested information on our Equity Plan for Improving Quality in Medicare (also referred to as the CMS Framework for Health Equity),¹⁰⁵ which outlines our commitment to close health equity gaps through improved data collection, measurement, and analysis of disparities across programs and policies. The request for information asked for public comment regarding the potential

⁹⁷ Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. 2011. Readmission Rates for Hispanic Medicare Beneficiaries with Heart Failure and Acute Myocardial Infarction. *Am Heart J.*, 162(2), 254–261 e253. Available at: <https://doi.org/10.1016/j.ahj.2011.05.009>

⁹⁸ Centers for Medicare & Medicaid Services. 2014. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures. Available at: <https://www.hhs.gov/guidance/document/medicare-hospital-quality-chartbook-performance-report-outcome-measures>.

⁹⁹ CMS Office of Minority Health. Updated August 2018. Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf

¹⁰⁰ Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. 2013. Chronic Obstructive Pulmonary Disease Readmissions at Minority-Serving Institutions. *Ann Am Thorac Soc.*, 10(6), 680–684. Available at: <https://doi.org/10.1513/AnnalsATS.201307-223OT>.

¹⁰¹ Joynt KE, Orav E, Jha AK. 2011. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA*, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

¹⁰² Nelson AR. 2003. Unequal Treatment: Report of the Institute of Medicine on Racial and Ethnic Disparities in Healthcare. *The Annals of thoracic surgery*, 76(4), S1377-S1381. doi: 10.1016/s0003-4975(03)01205-0.

¹⁰³ Peek, ME, Odoms-Young, A, Quinn, MT, Gorawara-Bhat, R, Wilson, SC, & Chin, MH. 2010. Race and Shared Decision-Making: Perspectives of African-Americans with diabetes. *Social Science & Medicine*, 71(1), 1–9. Available at: doi:10.1016/j.socscimed.2010.03.014.

¹⁰⁴ Department of Health and Human Services. 2021. Healthy People 2020: Disparities. Available at: www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.

¹⁰⁵ Centers for Medicare and Medicaid Services. 2022. CMS Framework for Health Equity 2022-2032. Available at: <https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf>. Centers for Medicare & Medicaid Services. 2021. Paving the Way to Equity: A Progress Report. Available at:

<https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>. Accessed on February 20, 2023. See also, Centers for Medicare & Medicaid Services Office of Minority Health. 2021. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input. Accessed on February 20, 2023.

stratification of quality measure results by race and ethnicity and the potential creation of a hospital or facility equity score in CMS quality reporting and value-based purchasing programs, including the ESRD QIP. We received many responses to that request for public comment, and we refer readers to the CY 2022 ESRD PPS final rule for summaries of those comments (86 FR 61934 through 61937). We noted in the CY 2022 ESRD PPS final rule the value of these comments in the continuing development of our health equity quality measurement efforts, and we stated that we would take the comments into account for future development and expansion of our health equity quality measurement efforts.

The Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission have independently concluded that facility leadership plays an important role in promoting a culture of quality and safety.^{106,107,108} AHRQ research shows that facility boards can influence quality and safety in a variety of ways; not only through strategic initiatives, but also through more direct interactions with frontline workers.¹⁰⁹ The Joint Commission found that a leader who is committed to prioritizing and making patient safety visible through every day actions is a critical part of creating a true culture of safety, which in turn fosters an organizational culture in which patients are treated with dignity and respect.¹¹⁰ Because CMS is also working toward the goal of all patients receiving high-quality healthcare, regardless of individual characteristics, we are also committed to supporting healthcare organizations in building a culture of safety *and* equity that focuses on educating and empowering their workforce to recognize and eliminate

¹⁰⁶ Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019. Available at: <https://psnet.ahrq.gov/primer/leadership-role-improving-safety>.

¹⁰⁷ Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: <https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf>.

¹⁰⁸ See information on launch of new “Health Care Equity Certification” in July 2023 from Joint Commission on Accreditation of Healthcare Organizations, USA, available at: <https://www.jointcommission.org/our-priorities/health-care-equity/health-care-equity-prepublication/>.

¹⁰⁹ Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019: Available at: <https://psnet.ahrq.gov/primer/leadership-role-improving-safety>.

¹¹⁰ Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: <https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf>.

health disparities. This includes patients receiving the right care, at the right time, in the right setting for their condition(s), regardless of those characteristics.

We believe that strong and committed leadership from dialysis facility executives and board members is essential and can play a role in shifting organizational culture and advancing equity goals for dialysis facilities. Studies demonstrate that hospital leadership can positively influence culture for better quality, patient outcomes, and experience of care.^{111,112,113} A systematic review of 122 published studies showed that strong leadership that prioritized safety, quality, and the setting of clear guidance with measurable goals for improvement resulted in a high-performing hospital with better patient outcomes.¹¹⁴ We believe this conclusion also applies to dialysis facilities, and that the commitment of dialysis facility leadership to health equity would result in a reduction of health disparities in the ESRD population.

Our belief that a leadership commitment to health equity can lead to a reduction of health disparities is also supported by research conducted by the Institute for Healthcare Improvement (IHI), which studied 23 health systems throughout the U.S. and Canada. The IHI's research showed that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among populations that have been disadvantaged by the healthcare system.¹¹⁵ This IHI study specifically identified concrete actions to make advancing health equity a core strategy, including establishing this goal as a leader-driven priority alongside organizational development structures and processes.¹¹⁶ Based upon

¹¹¹ Bradley EH, Brewster AL, McNatt Z, et al. (2018) How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. *BMJ Qual Saf.*, 27(3), 218-225. doi:10.1136/bmjqs-2017-006574.

¹¹² Smith SA, Yount N, Sorra J. 2017. Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. *BMC Health Services Research*, 17(1), 143. doi:10.1186/s12913-017-2078-6.

¹¹³ Keroack MA, Youngberg BJ, Ceresse JL, Krsek C, Prellwitz LW, Trevelyan EW. (2007). Organizational Factors Associated with High Performance in Quality and Safety in Academic Medical Centers. *Acad Med.*, 82(12), 1178-86. doi: 10.1097/ACM.0b013e318159e1ff.

¹¹⁴ Millar R, Mannion R, Freeman T, et al. (2013). Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. *The Milbank quarterly*, 91(4), 738-70. doi:10.1111/1468-0009.12032.

¹¹⁵ Mate KS and Wyatt R. 2017. Health Equity Must Be a Strategic Priority. *NEJM Catalyst*. Available at: <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556>.

¹¹⁶ Mate KS and Wyatt R. 2017. Health Equity Must Be a Strategic Priority. *NEJM Catalyst*. Available at: <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556>.

these findings, we believe that dialysis facility leadership can be instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity goals and ensuring high-quality care at dialysis facilities is accessible to all. Based on this well-developed body of evidence, we are proposing to adopt an attestation-based structural reporting measure, Facility Commitment to Health Equity, for the ESRD QIP beginning with PY 2026.

The first pillar of our strategic priorities¹¹⁷ reflects our deep commitment to improvements in health equity by addressing the health disparities that underly our health system. In line with this strategic pillar, we developed this structural measure to assess facility commitment to health equity across five domains (see Table 13 below) using a suite of organizational competencies aimed at achieving health equity for all patients, including but not limited to patients who belong to racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe these elements are actionable focus areas, and assessment of dialysis facility leadership commitment to them is foundational.

We are proposing to adopt the measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP. Disparities in health equity are tied to worse patient outcomes in the ESRD community. For example, individuals from racial and ethnic minority groups and with lower incomes are less likely to receive recommended care for CKD risk factors and are also less likely to reduce CKD risk through

¹¹⁷ Brooks-LaSure, C. 2021. My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: <https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms>.

recommended treatment goals.^{118,119,120,121} Consequently, some groups are more likely to progress from CKD to ESRD and less likely to be under the care of a nephrologist before starting dialysis.¹²² Individuals from racial and ethnic minority groups with ESRD are more likely to have 30-day hospital readmissions when compared to non-Hispanic White patients.¹²³ We believe that this measure is an appropriate measure of ESRD quality of care because it would improve facilities' awareness of the tie between their structural practices and their patient outcomes by reporting these data, thus informing facility practices such that their patients attain better outcomes. We also believe that the proposed measure would incentivize facilities to collect and utilize their data to identify their own critical equity gaps, implement plans to address said gaps, and ensure that they dedicate resources to addressing those gaps. Facilities could analyze data to understand, for example, whether there are any demographic factors (such as race, national origin, primary language, and ethnicity), or social drivers of health (such as housing status and food security) that may be affecting access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. Thus, the measure aims to support facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources. While the measure does not require facilities to take specific actions, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the proposed measure is intended

¹¹⁸ United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

¹¹⁹ Benjamin O, Lappin SL. End-Stage Renal Disease. Updated 2021 Sep 16. In: Stat Pearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK499861/>.

¹²⁰ Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. *Seminars in Dialysis* 30(3):213-223. doi:10.1111/sdi.12589.

¹²¹ CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: <https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf>.

¹²² Norton, J. M., Moxey-Mims, M. M., Eggers, P. W., Narva, A. S., Star, R. A., Kimmel, P. L., & Rodgers, G. P. (2016). Social Determinants of Racial Disparities in CKD. *Journal of the American Society of Nephrology: JASN*, 27(9), 2576–2595. <https://doi.org/10.1681/ASN.2016010027>

¹²³ CMS (2014). Health Disparities Among Aged ESRD Beneficiaries, 2014. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf>.

to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a state’s civil rights laws.

The five questions of the proposed structural measure are adapted from the CMS Office of Minority Health’s Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.¹²⁴ We have already adopted this measure for the Hospital Inpatient Quality Reporting (IQR) Program, and we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49201) for a discussion of the measure in that program. Other than replacing the term “hospital” with the term “facility,” the proposed measure is identical to the Hospital IQR Program measure. The Facility Commitment to Health Equity measure is aligned with the Meaningful Measures Area of “Equity of Care” and the Meaningful Measures 2.0 goal to “Leverage Quality Measures to Promote Equity and Close Gaps in Care” because it seeks to assess structural health equity issues that could inform facility practices such that their patients attain better outcomes. This measure also supports the Meaningful Measures 2.0 objective to “[c]ommit to a patient-centered approach in quality measure and value-based incentives programs to ensure that quality and safety measures address healthcare equity” because the measure would incentivize facilities to identify their own healthcare equity gaps from a structural perspective.

b. Overview of Measure

The proposed Facility Commitment to Health Equity reporting measure would assess dialysis facility commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for all populations, including those that have been disadvantaged, marginalized, and underserved by the healthcare system. As previously noted, this includes, but is not limited to: racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural

¹²⁴ Centers for Medicare & Medicaid Services. 2021. Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf>.

populations, religious minorities, and people facing socioeconomic challenges. Table 13 includes the five attestation domains and the elements within each of those domains to which a facility would report an affirmative attestation for the facility to receive points for that domain.

TABLE 13: The Facility Commitment to Health Equity Measure’s Five Attestations

Attestation	Elements: Select all that apply
(Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)	
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.	<p>(A) Our facility strategic plan identifies priority populations who currently experience health disparities.</p> <p>(B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals.</p> <p>(C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals.</p> <p>(D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.</p>
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.	<p>(A) Our facility collects demographic information (such as self-reported race, national origin, primary language, and ethnicity data) and/or social determinant of health information on the majority of our patients.</p> <p>(B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information.</p> <p>(C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using certified EHR technology.</p>
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.	(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.
Domain 4: Quality Improvement	

Health disparities are evidence that high-quality care has not been delivered equitably to all patients.* Engagement in quality improvement activities can improve quality of care for all patients.

(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.

Domain 5: Leadership Engagement

Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.

(A) Our facility senior leadership, including chief executives and the entire facility** board of trustees, annually reviews our strategic plan for achieving health equity.

(B) Our facility senior leadership, including chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

* After publication of the “List of Measures Under Consideration for December 1, 2022” (2022 MUC List), we clarified the language in Domain 4: “Health disparities are evidence that high quality care has not been delivered *equitably* to all patients.”

** After publication of the 2022 MUC List, we identified that Domain 5 incorrectly referred to the “hospital board of trustees” instead of the “facility board of trustees,” and therefore updated the language in Domain 5 to be more applicable to the ESRD QIP.

c. Measure Calculation

The proposed Facility Commitment to Health Equity measure consists of five attestation-based questions, each representing a separate domain of commitment. For a facility to affirmatively attest “yes” to a domain, and receive points for that domain, the facility would need to determine that it engages in all of the activities that are included as elements under the domain. A facility that engages in all of the activities for a domain would report an affirmative attestation by answering “yes” to the attestation-based question for that domain. There is no option for a facility to answer “yes” in response to an attestation-based question for a domain if the facility engages in some, but not all, of the activities included as domain elements, and there is also no option for a facility to answer “no” in response to any attestation-based question for a domain. The measure would be expressed as a fraction, and a facility can score either 0, 2, 4, 6, 8, or 10 for the performance period, depending on the number of domains to which a facility positively attests. We are proposing that the measure denominator would be “ten,” with each domain being represented as two points out of that total ten points, and that the numerator would be calculated as two points for each “yes” answer the facility reports which are then summed together. We chose to award facilities two points for each affirmative response to an attestation-

based question so that the maximum number of points a facility could receive for the measure is ten, which is the same maximum number of points that a facility can receive on other ESRD QIP measures.

For example, for Domain 1 (“Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority”), a facility would evaluate and determine whether its strategic plan satisfies all of the elements described in (A) through (D) (see Table 13). If the facility’s plan satisfies all four of these elements, the facility would respond “yes” to the attestation-based question for Domain 1 and receive two (2) points for that response. If the facility determined that its strategic plan satisfies elements (A) and (B) but not (C) and (D), the facility would not be able to respond “yes” to Domain 1 and would not receive any points for that domain.

The numerator would be calculated as the sum of the points the facility earns for responding “yes” to the attestation-based questions. For example, a facility that responds “yes” to all five attestation-based questions would receive the maximum 10 points (two points for each of the five “yes” responses). A facility that responds “yes” to three of the attestation-based questions would receive six points.

We are proposing that the Facility Commitment to Health Equity reporting measure would be added to the Reporting Measure Domain, as discussed further in section IV.C.6 of this proposed rule. Technical specifications for the proposed measure can be found in the ESRD QIP CY 2024 Technical Measure Specifications, which are available at:

https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/esrdqip/061_technicalspecifications. Consistent with case minimums we have adopted for our other ESRD QIP reporting measures, we are proposing that facilities must have 11 qualifying patients and a CCN open date before September 1 of the performance period that applies to the program year in order to be eligible for scoring on the Facility Commitment to Health Equity reporting measure.

d. Data Submission and Reporting

We are proposing that facilities would be required to submit data needed to calculate the Facility Commitment to Health Equity measure once on an annual basis using EQRS beginning with PY 2026. We are proposing that the deadline for submission would be the end of the EQRS December data reporting month for the applicable performance period, which is consistent with current reporting deadlines for other ESRD QIP measures. For example, for the PY 2026 ESRD QIP, facilities would need to report data on the measure by the end of the December data reporting month in CY 2024. As described in Table 17 of this proposed rule, we are proposing performance standards for the Facility Commitment to Health Equity reporting measure. We are proposing a 12-month performance period for the measure. We are also proposing that facilities would be required to follow the submission and reporting requirements for web-based measures for the ESRD QIP posted on the QualityNet website: <https://qualitynet.cms.gov/esrd/esrdqip>.

e. Review by the Measure Applications Partnership

We included the Facility Commitment to Health Equity measure as a measure under consideration for the ESRD QIP on the publicly available “List of Measures Under Consideration for December 1, 2022” (MUC List), a list of measures under consideration for use in various Medicare quality programs.¹²⁵ The CBE-convened Measure Applications Partnership (MAP) Health Equity Advisory Group reviewed the MUC List and the Facility Commitment to Health Equity measure (MUC2022–027) in detail on December 6-7, 2022.¹²⁶ The Health Equity Advisory Group expressed concern that this is more of a “checklist” measure that may not directly address health inequities at a systemic level, but the advisory group generally agreed that a structural measure such as this one represents progress toward improving equitable care.¹²⁷ In addition, on December 8-9, 2022, the MAP Rural Health Advisory Group reviewed the 2022

¹²⁵Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. Available at: <https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx>.

¹²⁶Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹²⁷Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

MUC List, and the MAP Hospital Workgroup reviewed the 2022 MUC List on December 13-14, 2022.¹²⁸ The MAP Hospital Workgroup recognized that reducing health care disparities would represent a substantial benefit to overall quality of care, but expressed reservations about the measure's link to clinical outcomes; the MAP Hospital Workgroup members voted to conditionally support the measure for rulemaking pending: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results; and (4) verifying attestation provided by the accountable entities.¹²⁹ Thereafter, the MAP Coordinating Committee deliberated on January 24-25, 2023 and ultimately voted to conditionally support the Facility Commitment to Health Equity measure for rulemaking with the same conditions.¹³⁰

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

¹²⁸ Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Rural Health Advisory Group, at <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>; see also, MAP Hospital Workgroup, available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹²⁹ Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹³⁰ Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

We are proposing to publicly display the facility-specific results for the Facility Commitment to Health Equity reporting measure on an annual basis through our *Care Compare* website at: <https://www.medicare.gov/care-compare/>. We anticipate making the first public report available in January 2026.

We invite public comment on this proposal.

3. Proposed Modification of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning with PY 2026

a. Background

On January 31, 2020, the Secretary of the Department of Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–COV–2, a novel (new) coronavirus that causes a disease named “coronavirus disease 2019” (COVID–19).¹³¹ Subsequently, the measure was adopted across multiple quality reporting programs including the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), the Hospital Inpatient Quality Reporting Program (86 FR 45374), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Outpatient Quality Reporting Program (86 FR 63824 through 63833), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Ambulatory Surgical Center Quality Reporting Program (86 FR 63875 through 63883), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396). COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.1 million deaths in the United States as of March 27, 2023.¹³² In recognition of the ongoing significance

¹³¹ U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. 2020. Determination that a Public Health Emergency Exists. Available at: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

¹³² Centers for Disease Control and Prevention. COVID Data Tracker. Accessed March 27, 2023. Available at: <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

and complexity of COVID–19, the Secretary has renewed the PHE on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 9, 2023.¹³³ The PHE expired on May 11, 2023; however, HHS has stated that the public health response to COVID–19 remains a public health priority with a whole of government approach to combatting the virus, including through vaccination efforts.¹³⁴

As we stated in the CY 2023 ESRD PPS final rule (87 FR 67244) and in our Revised Guidance for Staff Vaccination Requirements,¹³⁵ vaccination is a critical part of the nation’s strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including dialysis facilities, in order to protect health care workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities throughout the PHE and beyond. Prior to the publication of the CY 2023 ESRD PPS final rule on November 7, 2022, the FDA had approved or issued emergency use authorizations (EUAs) for COVID-19 vaccines for adults manufactured by Pfizer-BioNTech,¹³⁶ Moderna,¹³⁷ and Janssen.¹³⁸ The populations for which all three vaccines were authorized at that time included individuals 18 years of age and older, and the Pfizer-BioNTech vaccine was authorized for ages 12 and older. The FDA issued an approval for the Pfizer-BioNTech vaccine,

¹³³ U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. 2023. Renewal of Determination that a Public Health Emergency Exists. Available at: <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx>.

¹³⁴ U.S. Dept. of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>.

¹³⁵ Centers for Medicare & Medicaid Services. Revised Guidance for Staff Vaccination Requirements QSO-23-02-ALL. October 26, 2022. Available at: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>.

¹³⁶ Food and Drug Administration. December 2020. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>.

¹³⁷ Food and Drug Administration. December 2020. FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid>.

¹³⁸ Food and Drug Administration. February 2021. FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine>.

now marketed as Comirnaty, on August 23, 2021.¹³⁹ Additionally, the FDA issued approval for the Moderna vaccine, marketed as Spikevax, on January 31, 2022¹⁴⁰ and an EUA for the Novavax adjuvanted vaccine on July 13, 2022.¹⁴¹ The FDA also issued EUAs for single booster doses of the then-authorized COVID-19 vaccines. As of November 19, 2021,^{142,143,144} a single booster dose of each COVID-19 vaccine was authorized for all eligible individuals 18 years of age and older. EUAs were subsequently issued for a second booster dose of the Pfizer-BioNTech and Moderna vaccines in certain populations in March 2022.¹⁴⁵ FDA first authorized the use of a booster dose of bivalent or “updated” COVID-19 vaccines from Pfizer-BioNTech and Moderna in August 2022.¹⁴⁶

We stated in the CY 2023 ESRD PPS final rule that HCP are at risk of carrying COVID-19 infection to patients, experiencing illness or death themselves as a result of contracting COVID-19, and transmitting COVID-19 to their families, friends, and the general public (87 FR 67244). While the impact of COVID-19 vaccines on asymptomatic infection and transmission is not yet fully known, there is now robust data available on COVID-19 vaccine effectiveness across multiple populations against symptomatic infection, hospitalization, and

¹³⁹ Food and Drug Administration. August 2021. FDA Approves First COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

¹⁴⁰ Food and Drug Administration. January 2022. Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>.

¹⁴¹ Food and Drug Administration. July 2022. Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted>.

¹⁴² Food and Drug Administration. September 2021. FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations. Available at: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations>.

¹⁴³ Food and Drug Administration. October 2021. Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines>.

¹⁴⁴ Food and Drug Administration. November 2021. Coronavirus (COVID-19) Update: FDA Expands Eligibility for COVID-19 Vaccine Boosters. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters>.

¹⁴⁵ Food and Drug Administration. March 2022. Coronavirus (COVID-19) Update: FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and>.

¹⁴⁶ Food and Drug Administration. August 2022. Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use>.

death. Two-dose COVID–19 vaccines from Pfizer-BioNTech and Moderna were found to be 88 percent and 93 percent effective against hospitalization for COVID–19, respectively, over 6 months for adults over age 18 without immunocompromising conditions.¹⁴⁷ During a SARS–COV–2 surge in the spring and summer of 2021, 92 percent of COVID–19 hospitalizations and 91 percent of COVID–19-associated deaths were reported among persons not fully vaccinated.¹⁴⁸ Real-world studies of population-level vaccine effectiveness indicated similarly high rates of effectiveness in preventing SARS–COV–2 infection among frontline workers in multiple industries, with a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.¹⁴⁹ Vaccines have also been highly effective in real-world conditions preventing COVID-19 in HCP with up to 96 percent effectiveness for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.¹⁵⁰ In the presence of high community prevalence of COVID–19, residents of nursing homes with low staff vaccination coverage had higher rates of COVID–19 cases and COVID–19 related deaths than those among residents of nursing homes with high staff vaccination coverage.¹⁵¹ Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, including hospitalization and death.

¹⁴⁷ Centers for Disease Control and Prevention. September 24, 2021. Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions – United States, March–August 2021. Available at: https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w.

¹⁴⁸ Centers for Disease Control and Prevention. September 10, 2021. Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status – 13 U.S. Jurisdictions, April 4–July 17, 2021. Available at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm>.

¹⁴⁹ Centers for Disease Control and Prevention. August 27, 2021. Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID-19 Vaccines in Preventing SARS-COV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance – Eight U.S. Locations, December 2020–August 2021. Available at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm>.

¹⁵⁰ Pilishivi, T. et al. (December 2022). Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. *New England Journal of Medicine*. 2021 Dec 16;385(25):e90. Available online at: <https://pubmed.ncbi.nlm.nih.gov/34551224/>.

¹⁵¹ McGarry BE et al. (January 2022). Nursing Home Staff Vaccination and Covid-19 Outcomes. *New England Journal of Medicine*. 2022 Jan 27;386(4):397–398. Available online at: <https://pubmed.ncbi.nlm.nih.gov/34879189/>.

As SARS–COV–2 persists and evolves, our COVID–19 vaccination strategy must remain responsive. When we finalized adoption of the COVID-19 Vaccination Coverage Among HCP measure in the CY 2023 ESRD PPS final rule, we stated that HCP should be counted as vaccinated if they received COVID-19 vaccination any time from when it first became available in December 2020 (87 FR 67247). We noted that a completed vaccination course, defined for purposes of the measure as the primary vaccination series, may require one or more doses depending on the specific vaccine used, and that the NHSN application automatically calculates the total value for “Any completed COVID-19 vaccine series.” We also stated that, as vaccination protocols continue to evolve, we will continue to work with the CDC to update relevant measure specifications as necessary. Since we finalized the COVID-19 Vaccination Coverage Among HCP measure in the CY 2023 ESRD PPS final rule, new variants of SARS–COV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a variant of concern by the CDC because it spreads more easily than earlier variants.¹⁵² Vaccine manufacturers have responded to the Omicron variant by developing bivalent COVID–19 vaccines, which include a component of the original virus strain to provide broad protection against COVID–19 and a component of the Omicron variant to provide better protection against COVID–19 caused by the Omicron variant.¹⁵³ These booster doses of the bivalent COVID–19 vaccines have been shown to increase immune response to SARS–COV–2 variants, including Omicron, particularly in individuals who are more than 6 months removed from receipt of their primary series.¹⁵⁴ The FDA issued EUAs for booster doses of two bivalent COVID–19 vaccines, one from Pfizer-BioNTech¹⁵⁵ and one

¹⁵² Food and Drug Administration. August 2021. Variants of the Virus. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html>.

¹⁵³ Food and Drug Administration. November 2022. COVID–19 Bivalent Vaccine Boosters.

¹⁵⁴ Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. *Clin Microbiol Infect.* 2022 May;28(5):735.e1-735.e3. Available online at: <https://pubmed.ncbi.nlm.nih.gov/35143997/>.

¹⁵⁵ Food and Drug Administration. November 2022. Pfizer-BioNTech COVID–19 Vaccines. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines>.

from Moderna,¹⁵⁶ and strongly encourages anyone who is eligible to consider receiving a booster dose with a bivalent COVID-19 vaccine to provide better protection against currently circulating variants.¹⁵⁷ COVID-19 booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination,^{158 159} with a rate of breakthrough infections among HCP who received only a two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.¹⁶⁰ Data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across facilities.

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs issued by the FDA for bivalent boosters, the continued presence of SARS–COV–2 in the United States, and variance among rates of booster dose vaccination, it is important to modify the COVID–19 Vaccination Coverage Among HCP measure to reflect recent updates that explicitly specify for HCP to receive primary series and booster vaccine doses in a timely manner. As the COVID–19 pandemic persists, we continue to believe that monitoring and surveillance is important and provides patients, beneficiaries, and their caregivers with information to support informed decision making. We propose to modify the COVID–19 Vaccination Coverage Among HCP measure to replace the term “complete vaccination course” with the term “up to date” in the HCP vaccination definition. We also

¹⁵⁶ Food and Drug Administration. November 2022. Moderna COVID–19 Vaccines. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines>.

¹⁵⁷ Food and Drug Administration. August 2022. Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use>.

¹⁵⁸ Prasad N et al. (May 2022). Effectiveness of a COVID-19 Additional Primary or Booster Vaccine Dose in Preventing SARS-CoV-2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant - United States, February 14-March 27, 2022. Morbidity and Mortality Weekly Report (MMWR). 2022 May 6;71(18):633-637. Available online at: <https://pubmed.ncbi.nlm.nih.gov/35511708/>.

¹⁵⁹ Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect. 2022 May;28(5):735.e1-735.e3. Available online at: <https://pubmed.ncbi.nlm.nih.gov/35143997/>.

¹⁶⁰ Ibid.

propose to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with PY 2026. As we stated in the CY 2023 ESRD PPS final rule (87 FR 67245), the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates. Unlike outcome measures, process measures do not assess a particular outcome.

b. Overview of Updated Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in settings such as dialysis facilities, and the measure is reported via the CDC’s National Healthcare Safety Network (NHSN).

We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67245 through 67246) for more information on the initial review of the measure by the Measure Applications Partnership (MAP). We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022-2023 pre-rulemaking cycle for consideration by the MAP. In December 2022, the MAP’s Hospital Workgroup discussed the modified measure. The Hospital Workgroup stated that the revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. Additionally, the Hospital Workgroup appreciated that the respecified proposed measure of the target population is broader and simplified from seven categories of HCP to four.¹⁶¹ During review, the MAP Health Equity Advisory Group highlighted the importance of COVID–19 measures and asked whether the measure excludes individuals with contraindications to FDA authorized or approved COVID-19 vaccines, and whether the measure will be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but the measure would not be stratified

¹⁶¹ Centers for Medicare & Medicaid Services. 2022-2023 Preliminary Analysis Worksheet. 2022. Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=97891>.

since the data are submitted at an aggregate rather than an individual level. The MAP Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually and that small rural facilities may not have employee health software.¹⁶² The measure developer acknowledged the challenge of getting adequate documentation and emphasized the goal to ensure the measure does not present a burden on the provider. The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified COVID–19 Vaccination Coverage Among HCP measure if vaccination strategy becomes seasonal. The revised measure received conditional support for rulemaking from both the MAP workgroups pending testing indicating the measure is reliable and valid, and endorsement by the consensus-based entity (CBE).¹⁶³ The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636).¹⁶⁴

(1) Measure Specifications

This reporting measure includes at least one week of data collection a month for each of the three months in a quarter. The denominator would be the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC. Facilities report the following four categories of HCP to NHSN:

1. Employees: includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.
2. Licensed independent practitioners (LIPs): This includes physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility but are not directly employed by it (that is, they do not receive a direct paycheck from the

¹⁶² Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹⁶³ In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

¹⁶⁴ Centers for Medicare & Medicaid Services. 3636 Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel. Accessed February 6, 2023. Available at: <https://www.qualityforum.org/QPS/3636>.

reporting facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.

3. Adult students/trainees and volunteers: This includes all medical, nursing, or other health professional students, interns, medical residents, and volunteers aged 18 or over who are affiliated with the healthcare facility, but are not directly employed by it (that is, they do not receive a direct paycheck from the facility), regardless of clinical responsibility or patient contact.

4. Other contract personnel: Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the previously discussed denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission in the NHSN application, but data for this category are not included in the COVID-19 Vaccination Coverage Among HCP measure.¹⁶⁵ The denominator excludes denominator-eligible individuals with contraindications as defined by the CDC.¹⁶⁶ There are no changes to the denominator exclusions.

The numerator is the cumulative number of HCP in the denominator population who are considered up to date with recommended COVID-19 vaccines. Facilities should refer to the definition of up to date as of the first day of the applicable reporting quarter, which can be found at <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf>. For example, for the proposed updated measure, HCP would be considered up to date during the applicable performance period for the ESRD QIP if they meet one of the following criteria:

1. Individuals who received an updated bivalent¹⁶⁷ booster dose, or

¹⁶⁵ For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID-19 Vaccination Protocol, Weekly COVID-19 Vaccination Module for Healthcare Personnel available at: <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf>.

¹⁶⁶ Centers for Disease Control and Prevention. 2022. Contraindications and precautions. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications>.

¹⁶⁷ The updated (bivalent) Moderna and Pfizer-BioNTech boosters target the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on 9/2/2022. As of this date, the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.

2a. Individuals who received their last booster dose less than 2 months ago, or

2b. Individuals who completed their primary series¹⁶⁸ less than 2 months ago.

We note that for purposes of NHSN surveillance, the CDC began using this definition of up to date during the quarter 4 2022 surveillance period (September 26, 2022 – December 25, 2022).

We refer readers to <https://www.cdc.gov/nhsn/nqf/index.html> for more details on the measure specifications. We note that the proposed updated COVID-19 Vaccination Coverage Among HCP measure will remain a reporting measure and that the proposed updates to measure weighting for PY 2026 and PY 2027 are discussed further in sections IV.C.6 and IV.D.7 of this proposed rule.

(2) Consensus-Based Entity Endorsement

The current version of the measure in the ESRD QIP received CBE endorsement (CBE #3636, “Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel”) on July 26, 2022. Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. When we adopted this measure in the CY 2023 ESRD PPS final rule, we reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies. The CDC, as the measure developer, is pursuing endorsement for the modified version of the measure.

¹⁶⁸ Completing a primary series means receiving a two-dose series of a COVID–19 vaccine or a single dose of Janssen/J&J COVID–19 vaccine.

c. Data Submission and Reporting

We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67246) for information on data submission and reporting for the measure. We are not proposing any changes to the existing data submission requirements.

We invite public comment on this proposal.

4. Proposal to Convert the Clinical Depression Screening and Follow-Up Reporting Measure to a Clinical Measure Beginning with the PY 2026 ESRD QIP

In the CY 2015 ESRD PPS final rule, we finalized the adoption of the Clinical Depression Screening and Follow-Up reporting measure, beginning in PY 2018 (79 FR 66200 through 66203). As we noted in the CY 2015 ESRD PPS final rule, depression is a highly prevalent condition in patients with ESRD, which impacts many aspects of a patient's life and is associated with higher rates of mortality in the ESRD population. Adoption of a measure that assesses whether facilities screen patients for depression, and develop follow-up plans when appropriate, was and still is an opportunity to improve the health of patients with ESRD.

In this proposed rule, we are proposing to convert the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure and to adopt a new methodology for scoring that measure as a clinical measure. We believe this proposal would help to ensure that the measure is scored in a manner that more closely aligns with current clinical guidelines for depression screening and follow-up because it narrows the number of conditions on which a facility can earn points.

Clinical guidelines indicate that providers should both screen for depression and develop a follow-up plan for patients who test positive for depression.¹⁶⁹ Screening for depression is an important aspect of ESRD patient care, especially because ESRD and depression may present with similar symptoms, including but not limited to fatigue, poor appetite, headaches, and lack of

¹⁶⁹ K/DOQI clinical practice guidelines for cardiovascular disease in dialysis patients| Volume 45, SUPPLEMENT 3, 16-153, April 2005. <https://doi.org/10.1053/j.ajkd.2005.01.019>.

focus.¹⁷⁰ Developing a follow-up plan for patients who screen positive for depression is equally important because ESRD patients may not be aware that they can seek treatment or that such treatment could be beneficial.¹⁷¹ Under the specifications of the current Clinical Depression Screening and Follow-Up reporting measure, facilities are required to report one of six conditions with respect to each eligible patient, and we calculate the measure rate for the facility as the percentage of eligible patients for which the facility reports one of those six conditions. The six conditions are as follows:

- Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
- Screening for clinical depression is documented as positive, and a follow-up plan is not documented, and the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given.
- Screening for clinical depression is documented as negative, and a follow-up plan is not required.
- Screening for clinical depression is not documented, but the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is not documented, and no reason is given.

We are not proposing to revise any of these conditions. However, we are proposing that we would convert the measure to a clinical measure and award credit to facilities only if they report one of the following four of those six conditions:

¹⁷⁰ PCORI Evidence Update. Treating Depression When You're on Dialysis (for Patients). July 2021. Available at: <https://www.pcori.org/sites/default/files/PCORI-Evidence-Update-for-Patients-Treating-Depression-When-Youre-on-Dialysis.pdf>.

¹⁷¹ Michael J Fischer, Elani Streja, Jui-Ting Hsiung, Susan T Crowley, Csaba P Kovesdy, Kamyar Kalantar-Zadeh, Wissam M Kourany, Depression screening and clinical outcomes among adults initiating maintenance hemodialysis, *Clinical Kidney Journal*, Volume 14, Issue 12, December 2021, Pages 2548–2555, <https://doi.org/10.1093/ckj/sfab097>.

- Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
- Screening for clinical depression is documented as positive, and a follow-up plan is not documented, and the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is documented as negative, and a follow-up plan is not required.
- Screening for clinical depression is not documented, but the facility possesses documentation stating the patient is not eligible.

If a facility selects one of the other two conditions (that is, “Screening for clinical depression is documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given” and “Screening for clinical depression is not documented, and no reason is given”), the facility would not receive credit in the numerator. We believe this proposed update is important because it would assess facility performance on both the clinical depression screening and the follow-up plan, to the extent that one is needed, and would also incentivize facilities to report the reason for either not documenting that they screened for clinical depression, or why they do not possess documentation of a follow-up plan. We believe that the performance score calculation methodology changes we are proposing to the Clinical Depression Screening and Follow-Up reporting measure would have a greater impact on fostering care coordination among providers and improving patient outcomes by incentivizing the documentation of depression screenings and follow-up plans, or alternatively requiring facilities to provide a reason why no screening or follow-up plan was documented. This proposed measure update would also align with our efforts under the Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.¹⁷² In

¹⁷² Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>.

2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.¹⁷³ We are addressing healthcare priorities and gaps with Meaningful Measures 2.0 by leveraging quality measures to increase efficiency, reduce burden, and close gaps in care. The proposed updates to the Clinical Depression Screening and Follow-Up measure would support these efforts and would align with several Meaningful Measures Areas, including “Seamless Care Coordination,” and “Behavioral Health,” as we believe that incentivizing the documentation of follow-up plans would encourage care coordination efforts to support the behavioral health outcomes of ESRD patients. The proposed modifications would also align with the Meaningful Measures 2.0 goal to “Leverage measures to drive outcome improvement through public reporting and payment programs” because we believe that converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure would help to drive outcome improvement through the ESRD QIP. Additionally, this proposed measure update would align with efforts to develop a Universal Foundation¹⁷⁴ that would help implement the vision outlined in our National Quality Strategy¹⁷⁵ and is fundamental to achieving several of the agency’s quality and value-based care goals.¹⁷⁶ Our proposal to update the Clinical Depression Screening and Follow-Up reporting measure would help to align the measure that is used in the ESRD QIP with the measure identified for use across multiple programs as part of the Behavioral Health domain of the Universal Foundation measure set.¹⁷⁷

¹⁷³ Centers for Medicare & Medicaid Services. 2021. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>. We note that Meaningful Measures 2.0 is still under development.

¹⁷⁴ Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher, L. Aligning Quality Measures across CMS — The Universal Foundation. The New England Journal of Medicine, February 1, 2023. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMp2215539>.

¹⁷⁵ Schreiber M, Richards AC, Moody-Williams J, Fleisher LA. The CMS National Quality Strategy: a person-centered approach to improving quality. Centers for Medicare and Medicaid Services, June 6, 2022 (<https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality>).

¹⁷⁶ Jacobs D, Fowler E, Fleisher L, Seshamani M. The Medicare value-based care strategy: alignment, growth, and equity. Health Affairs, July 21, 2022 (<https://www.healthaffairs.org/content/forefront/medicare-value-based-care-strategy-alignment-growth-and-equity>).

¹⁷⁷ Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher, L. Aligning Quality Measures across CMS — The Universal Foundation. The New England Journal of Medicine, February 1, 2023. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMp2215539>.

We are also proposing to convert the proposed updated version of the Clinical Depression Screening and Follow-Up measure to a clinical measure beginning with PY 2026, and to move that measure to the Care Coordination Measure Domain beginning with that payment year. We are proposing to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure because we believe that our proposed update to the performance score calculation aligns with that of a clinical measure. We are proposing to move the Clinical Depression Screening and Follow-Up measure from the Reporting Measure Domain to the Care Coordination Measure Domain because the updated clinical measure would no longer be appropriate for inclusion under the Reporting Measure Domain. We note that we are not proposing to change eligibility requirements for the measure. We discuss our proposed updates to measure domains and weights for PY 2026 in section IV.C.6 of this proposed rule.

We welcome public comment on our proposal to update the Clinical Depression Screening and Follow-Up measure and our proposal to convert it to a clinical measure beginning with PY 2026.

5. Proposal to Remove Two Measures from the ESRD QIP Measure Set, Beginning with PY 2026

We have undertaken efforts to review the existing ESRD QIP measure set to ensure continued clinical impact and effectiveness of the measures on facility performance. Based on that analysis and our evaluation of the Program's measures, we are proposing to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Ratio clinical measure beginning with PY 2026.

a. Proposal to Remove the Ultrafiltration Rate Reporting Measure from the ESRD QIP Measure Set Beginning with PY 2026

In the CY 2017 ESRD PPS final rule, we adopted the Ultrafiltration Rate reporting measure (81 FR 77912 through 77915). The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates (UFR) for each

qualifying patient. The Ultrafiltration Rate reporting measure is intended to guard against risks associated with high ultrafiltration (that is, rapid fluid removal) rates for adult dialysis patients undergoing hemodialysis (HD), because of indications that high ultrafiltration is an independent predictor of mortality. Faster ultrafiltration may lead to a number of health risks resulting from large volumes of fluid removed rapidly during each dialysis session, with deleterious consequences for the patient both in the short and longer term. When we added this measure to the ESRD QIP, we believed the documentation of the ultrafiltration measurements would ultimately contribute to the quality of the patient's ESRD treatment (81 FR 77912 through 77915).

More recent studies have indicated that the Ultrafiltration Rate reporting measure may not result in the intended patient outcomes. For example, a patient's body size may be a confounding, possibly explanatory factor for the relationship between higher UFR and increased mortality.¹⁷⁸ Additionally, although the Ultrafiltration Rate reporting measure captures a patient's UFR measurements reported monthly, the mortality risks associated with high UFR may be due to the frequency or number of HD sessions with high UFR.¹⁷⁹ We believe these findings show that the documentation of a patient's ultrafiltration measurements through the current Ultrafiltration Rate reporting measure may not necessarily indicate the quality of a patient's ESRD treatment and tracking the ultrafiltration rate as a quality indicator may influence decision-making regarding dialysis treatment. Therefore, a facility's performance on the measure may not accurately reflect the quality of care provided. Accordingly, we are proposing to remove this measure from the ESRD QIP measure set under measure removal factor 2 (performance or improvement on a measure does not result in better or the intended patient outcomes) beginning with the PY 2026 ESRD QIP.

¹⁷⁸ John T. Daugirdas and Daniel Schneditz. Seminars in Dialysis: Hemodialysis Ultrafiltration Rate Targets Should Be Scaled to Body Surface Area Rather than to Body Weight. 2017.

¹⁷⁹ Jose E. Navarrete, Ajai Rajabalan, Jason Cobb, and Janice P. Lea. Proportion of Hemodialysis Treatments with High Ultrafiltration Rate and the Association with Mortality. *Kidney360* 3: 1359–1366, 2022. doi: <https://doi.org/10.34067/KID.0001322022>.

We welcome public comment on our proposal.

b. Proposal to Remove the Standardized Fistula Rate Clinical Measure from the ESRD QIP Measure Set

In the CY 2018 ESRD PPS final rule, we adopted the Standardized Fistula Rate clinical measure (82 FR 50774 through 50777). Along with the Long-Term Catheter Rate clinical measure, we stated that the two vascular access measures, when used together, consider arteriovenous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients may exhaust their options for an AV fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all vascular access options. The Standardized Fistula Rate measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option by accounting for that possibility in the current measure specifications. In the CY 2018 ESRD PPS final rule, we stated that this paired incentive structure that relies on both measures reflects consensus best practice and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade (82 FR 50777).

Since the CY 2018 ESRD PPS final rule, there have been several changes to what many experts consider to be best practices with respect to vascular access in ESRD patients due to improvements in the care of ESRD patients overall, changes in patient demographics, and increasing patient longevity. Guidance published in 2019 by the National Kidney Foundation's Kidney Disease Outcome Quality Initiative (KDOQI) reflects updated best practices.¹⁸⁰ The KDOQI's 2019 guidance notes that prior guidelines and initiatives have emphasized a "fistula first" approach to vascular access choice due to the AV fistula's associations with better short-term results compared with other vascular access types.¹⁸¹ However, the 2019 guidance also

¹⁸⁰ Lok CE, Huber TS, Lee T, et al.; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. *Am J Kidney Dis.* 2020;75(4)(suppl 2):S1-S164.

¹⁸¹ KDOQI clinical practice guidelines for vascular access. *Am J Kidney Dis.* 2006;48:S176-S247.

notes that more recent data have challenged these associations because of the high complication rates of AV fistula maturation failure requiring intervention and increased acceptability of AV grafts. The guidance also encourages a more holistic, long-term approach to dialysis access that strives to preserve patient vasculature and avoid unnecessary procedures and complications. Therefore, following re-evaluation of this Fistula First approach, the KDOQI's 2019 guidance concludes that the Fistula First approach should no longer be considered a clinical best practice. Instead, the KDOQI's 2019 guidance concludes that a patient-centered approach to dialysis access that is based on a consideration of the patient's needs and individual factors is preferred. Providers should consider what would be most appropriate for the individual patient, including that AV fistula may not always be most appropriate based on the individual patient's needs and goals.

After considering these evolving best practices and the KDOQI's 2019 guidance, we have determined that the Standardized Fistula Rate Clinical Measure does not provide patients and their healthcare providers the necessary level of flexibility to choose the most suitable dialysis access. We believe that patients and their healthcare providers should have the flexibility to choose vascular access (either AV fistula or AV graft) where appropriate to their specific patient characteristics and treatment plans. This determination should be based on the healthcare provider's best clinical judgment that considers the vessel characteristics, patient comorbidities, health circumstances, and patient preference. Accordingly, we are proposing to remove the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026 under measure removal factor 3 (a measure no longer aligns with current clinical guidelines or practice).

We continue to consider both AV fistula and AV graft as preferable forms of vascular access to a long-term catheter, and evidence shows that long-term catheters should only be used

when all other AV access options have been exhausted.¹⁸² We also continue to believe that it is important to track the use of long-term catheters, minimize their use where possible, and incentivize best practices for vascular access. For those reasons, we are not proposing to remove the Long-Term Catheter Rate clinical measure.

We are also proposing to remove the reference to the Vascular Access Type Measure Topic and to assign the total weight of that topic (12 percent) solely to the Long-Term Catheter Rate clinical measure, as described in Table 15 of this proposed rule. We are proposing to assign the total weight to the Long-Term Catheter Rate clinical measure because we believe this continues to be an important measure of facility performance tied to improved patient outcomes. We believe that our proposal to assign the total 12 percent weight to the Long-Term Catheter Rate clinical measure will reflect our view that long-term catheter use is the least-favored vascular access treatment option, and should be avoided where more clinically preferable vascular access treatment options would be appropriate.

We welcome public comment on our proposal.

6. Proposed Revisions to Measure Domains and to Measure Weights Used to Calculate the Total Performance Score (TPS) Beginning with the PY 2026 ESRD QIP

In the CY 2023 ESRD PPS final rule (87 FR 67251 through 67254), we finalized revisions to the ESRD QIP measure domains beginning with PY 2025. Specifically, we added the Reporting Domain and updated measure domains and measure weights across five measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, Safety, and Reporting. The measure domains and weights we finalized in the CY 2023 ESRD PPS final rule are depicted in Table 14 below.

TABLE 14: Current PY 2026 ESRD QIP Measure Domains and Weights

Measure/Measure Topics by Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	12.00
SRB clinical measure	12.00
PPRW measure	6.00

¹⁸² See, e.g., Lee T, et al.; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164.

Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Vascular Access Type Measure Topic	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure	10.00
Reporting Measure Domain	10.00
Clinical Depression Screening and Follow-Up reporting measure	1.67
Hypercalcemia reporting measure	1.67
Ultrafiltration Rate reporting measure	1.67
MedRec reporting measure	1.67
NHSN Dialysis Event reporting measure	1.67
COVID-19 HCP Vaccination reporting measure	1.67

As discussed above, we are proposing that beginning with PY 2026, the Clinical Depression Screening and Follow-Up reporting measure would be converted to a clinical measure and included in the Care Coordination Domain, the Standardized Fistula Rate clinical measure would be removed from the Clinical Care Domain, the Ultrafiltration Rate reporting measure would be removed from the Reporting Domain, and the Facility Commitment to Health Equity reporting measure would be added to the Reporting Domain. To accommodate the new numbers of measures in the Care Coordination Domain, Clinical Care Domain, and Reporting Domain, we are proposing to update the individual measure weights in each of these domains. We believe that these proposed updates to the individual measure weights would help to ensure that a facility's individual measure performance has an appropriately proportionate impact on a facility's TPS, while also further incentivizing improvement on clinical measures. For example, for the Care Coordination Domain, we are proposing to update the measure weights for the SHR clinical measure and the SRR clinical measure to accommodate the inclusion of the proposed Clinical Depression Screening and Follow-Up clinical measure. We believe these newly proposed measure weights would strike an appropriate balance between the importance of facility performance on the SHR clinical measure and the SRR clinical measure on measuring patient outcomes, while also reflecting the impact of the proposed Clinical Depression Screening and Follow-Up clinical measure on patient quality of care. Additionally, the Vascular Access Type Measure Topic is currently weighted at 12 percent and includes both the Standardized

Fistula Rate clinical measure and the Long-Term Catheter Rate clinical measure. We are proposing to remove the Standardized Fistula Rate clinical measure and the Vascular Access Type Measure Topic, and we are also proposing to weight the Long-Term Catheter Rate clinical measure at 12 percent. We believe this proposal would incentivize improvement and reflect the impact of facility performance on the Long-Term Catheter Rate clinical measure (as the sole vascular access type measure) on patient outcomes. We continue to believe that patient outcomes improve when they receive the most clinically appropriate vascular access treatment option, and that long-term catheters should only be used when other vascular access treatment options are not feasible. Consistent with our approach in the CY 2023 ESRD PPS final rule, we are proposing to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure Domain so that each measure is weighted equally (87 FR 67251 through 67253). In light of these proposed updates to measures within the Reporting Measure Domain, we would weight each measure equally at 2 percent, which is consistent with our previously finalized approach to weight each measure in the Reporting Measure Domain equally. We note that although we are proposing to change the number of measures in three of the domains and the weights of certain individual measures in those domains, we are not proposing to change the weights of the five domains themselves because we believe the proposed updates to individual measures and measure weights do not significantly impact the measure domains themselves such that updating the weights of the measure domains would be required to accommodate the updated individual measure weights. The previously finalized and newly proposed measures that would be included in each domain, along with the proposed new measure weights, for PY 2026 are depicted in Table 15.

TABLE 15: Previously Finalized and Newly Proposed ESRD QIP Measure Domains and Weights for PY 2026

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	9.00

SRR clinical measure	9.00
PPPW measure	6.00
Clinical Depression Screening and Follow-Up measure*	6.00
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure	10.00
Reporting Measure Domain	10.00
Facility Commitment to Health Equity measure**	2.00
Hypercalcemia reporting measure	2.00
MedRec reporting measure	2.00
NHSN Dialysis Event reporting measure	2.00
COVID-19 HCP Vaccination reporting measure	2.00

*We are proposing to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

**We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

We welcome public comment on these proposals.

7. Performance Standards for the PY 2026 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively. For reporting measures, performance standards are the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure (42 CFR 413.178(a)(12)).

In the CY 2023 ESRD PPS final rule (87 FR 67259 through 67260), we set the performance period for the PY 2026 ESRD QIP as CY 2024 and the baseline period as CY 2022. In this proposed rule, we are estimating the performance standards for the PY 2026 clinical

measures in Table 5 using data from CY 2021, which was the most recent data available (87 FR 67260). For certain measures previously suppressed for the PY 2023 performance period due to significant impacts on the measure related to the COVID-19 public health emergency (87 FR 67225 through 67237), we used CY 2019 data. We intend to update these performance standards for all measures, using CY 2022 data, in the CY 2024 ESRD PPS final rule.

TABLE 16: Performance Standards for the Previously Finalized and Newly Proposed ESRD QIP Clinical Measures for PY 2026

Measure	Achievement Threshold (15 th Percentile of National Performance)	Median (50 th Percentile of National Performance)	Benchmark (90 th Percentile of National Performance)
Vascular Access Type (VAT)			
Long-Term Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Standardized Readmission Ratio ^a	34.27	26.97	17.02
NHSN BSI	0.833	0.290	0
Standardized Hospitalization Ratio ^b	187.80	148.33	105.54
Standardized Transfusion Ratio ^b	53.46	29.78	10.75
PPPW	8.12%	16.73%	33.90%
Clinical Depression*	80.95%	91.15%	100.00%
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	62.22%	76.57%
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%
*We are proposing to update the Clinical Depression Screening and Follow-Up measure beginning in PY 2026, as discussed in section IV.C.4 of this proposed rule.			

^aRate calculated as a percentage of hospital discharges

^bRate per 100 patient-years

Data sources: VAT measures: 2019 EQRS; SRR, SHR: 2019 Medicare claims; STTrR: 2021 Medicare claims; Kt/V: 2019 EQRS; Hypercalcemia: 2019 EQRS; NHSN: 2021 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 EQRS and 2019 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2021 EQRS.

In addition, we summarize in Table 17 requirements for successful reporting on previously finalized and newly proposed reporting measures for the PY 2026 ESRD QIP.

TABLE 17: Requirements for Successful Reporting of the Previously Finalized and Newly Proposed ESRD QIP Reporting Measures for PY 2026

Measure	Reporting Frequency	Data Elements
MedRec	Monthly	<ul style="list-style-type: none"> • Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: <ul style="list-style-type: none"> o physician, o nurse, o advanced registered nurse practitioner (ARNP), o physician assistant (PA), o pharmacist, or o pharmacy technician personnel • Name of eligible professional
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: <ul style="list-style-type: none"> • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
Hypercalcemia	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 Vaccination Coverage Among HCP*	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received an up to date vaccination course against SARS-CoV-2.
Facility Commitment to Health Equity**	Annually	Domains to which facility must attest affirmatively: <ul style="list-style-type: none"> • Equity is a Strategic Priority • Data Collection • Data Analysis • Quality Improvement • Leadership Engagement

* We are proposing to update the COVID-19 Coverage Among HCP reporting measure beginning with PY 2026, as discussed in section IV.C.3 of this proposed rule.

** We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

8. Eligibility Requirements for the PY 2026 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 18a.

TABLE 18a: Current Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula Rate (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients

Measure	Minimum data requirements	CCN open date	Small facility adjuster
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)**	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)***	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage Among HCP (Reporting)****	N/A	Before September 1 of the performance period that applies to the program year.	N/A

* We are proposing to remove the Standardized Fistula Rate clinical measure beginning in PY 2026, as discussed in section IV.C.5 of this proposed rule, and removed from Table 18b below.

** We are proposing to update the Clinical Depression Screening and Follow-Up measure and convert it to a clinical measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

*** We are proposing to remove the Ultrafiltration Rate reporting measure beginning in PY 2026, as discussed in section IV.C.5 of this proposed rule, and removed from Table 18b below.

**** We are proposing to update the COVID-19 Vaccination Coverage Among HCP measure beginning with PY 2026, as discussed in section IV.C.3 of this proposed rule.

We are proposing to add eligibility requirements for the new measures we are proposing beginning with the PY 2026 ESRD QIP. Our previously finalized and proposed new minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 18b.

TABLE 18b: Previously Finalized and Proposed New Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance	11-25 qualifying patients

Measure	Minimum data requirements	CCN open date	Small facility adjuster
		period that applies to the program year.	
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Clinical)*	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage Among HCP (Reporting)**	N/A	Before September 1 of the performance period that applies to the program year.	N/A
Facility Commitment to Health Equity (Reporting)***	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	

* We are proposing to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

** We are proposing to update the COVID-19 Vaccination Coverage Among HCP measure beginning with PY 2026, as discussed in section IV.C.3 of this proposed rule.

*** We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

9. Payment Reduction Scale for the PY 2026 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at 42 CFR 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period, it performed at the

50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Under our current policy, which is codified at 42 CFR 413.177 of our regulations, we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS (76 FR 634 through 635).

For PY 2026, we estimate using available data that a facility must meet or exceed a mTPS of 52 to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2021 and CY 2019 instead of the PY 2026 baseline period (CY 2022) because CY 2022 data are not yet available. We will update and finalize the mTPS and associated payment reduction ranges using CY 2022 data in the CY 2024 ESRD PPS final rule.

TABLE 19: Estimated Payment Reduction Scale for PY 2026 Based on the Most Recently Available Data

<u>Total performance score</u>	<u>Reduction (%)</u>
100-52	0%
51-42	0.5%
41-32	1.0%
31-22	1.5%
21-0	2.0%

D. Proposed Updates to Requirements Beginning with the PY 2027 ESRD QIP

1. PY 2027 ESRD QIP Measure Set

Under our current policy, we generally retain all measures once adopted for a payment year for subsequent payment years. In this proposed rule, we are proposing to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027.

TABLE 20: Proposed PY 2027 ESRD QIP Measure Set

Consensus -Based Entity (CBE) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure Percentage of HCP who receive a complete COVID-19 vaccination course.
N/A	Facility Commitment to Health Equity, a reporting measure Facilities will receive one point each for attesting to five different domains of commitment to advancing health equity for a total of five points.
N/A	Screening for Social Drivers of Health, a reporting measure* Percentage of patients at a dialysis facility who are 18 years or older screened for all five health-related social needs (HRSNs) (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety).

Consensus -Based Entity (CBE) #	Measure Title and Description
N/A	Screen Positive Rate for Social Drivers of Health, a reporting measure** Percentage of patients at a dialysis facility who are 18 years or older screened for all five HRSNs, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation problems, utility difficulties, or interpersonal safety.

* We are proposing to add the Screening for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.2 of this proposed rule.

** We are proposing to add the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.3 of this proposed rule.

2. Proposal to Adopt the Screening for Social Drivers of Health Reporting Measure Beginning with PY 2027

Our commitment to supporting facilities in building equity into their health care delivery practices is, in part, focused on empowering their workforce to recognize and eliminate health disparities that disproportionately impact their patients who have health-related social needs (HRSNs). HRSNs are significant risk factors associated with worse health outcomes as well as increased health care utilization.¹⁸³ We believe that the identification of HRSNs among facility patients has two significant benefits. First, research has shown that certain HRSNs disproportionately impact populations that have historically been underserved by the healthcare system and screening helps identify individuals who may have HRSNs.¹⁸⁴ Due to the association between chronic condition risk and HRSNs, screening for these needs could serve as evidence-based building blocks for supporting ESRD facilities in addressing persistent disparities and tracking progress towards closing the health equity gap in the ESRD population. Second, we believe HRSN screening by facilities could enable them to engage in meaningful collaboration with other healthcare providers and community-based organizations as part of a more holistic approach to addressing health equity gaps that negatively impact their ESRD

¹⁸³ Centers for Medicare & Medicaid Services. 2021. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>. Accessed: November 23, 2021.

¹⁸⁴ American Hospital Association. 2020. Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at: https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.

patients, which may also eventually result in implementing and evaluating related innovations in health and social care delivery among these facilities, healthcare providers and community-based organizations.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220), we finalized the adoption of two evidence-based measures in the Hospital Inpatient Quality Reporting Program, the Screening for Social Drivers of Health and the Screen Positive Rate for Social Drivers of Health measures. These two Social Drivers of Health measures support identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients. These measures also encourage hospitals to systematically collect HRSN data. We have also finalized a policy requiring that all Special Needs Plans (SNPs) include one or more questions on housing stability, food security, and access to transportation in their Health Risk Assessment (HRA) using questions from a list of screening instruments specified in sub-regulatory guidance (87 FR 27726 through 27740), as well as adopted the Screening for Social Drivers of Health Measure in the Merit-based Incentive Payment System Program (87 FR 70054 and 70055).

Advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars and a Biden-Harris Administration priority.¹⁸⁵ We believe that the proposed Screening for Social Drivers of Health reporting measure aligns with *The CMS Quality Strategy Goals* for effective care coordination and prevention and treatment of chronic conditions.¹⁸⁶ The proposed Screening for Social Drivers of Health reporting measure would enable facilities to identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes. Improvement in risk identification has the potential to reduce healthcare access barriers, address the disproportionate expenditures attributed to

¹⁸⁵ Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: <https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms>.

¹⁸⁶ Centers for Medicare & Medicaid Services. (2021) CMS National Quality Strategy. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>

populations with greatest risk, and improve the facility's quality of care through the facility taking steps to mitigate poor health outcomes by improving their care coordination efforts.^{187,188,189,190} These data could help facilities improve their care coordination efforts, including by understanding what HRSNs might be contributing to poor patient outcomes so that facilities can direct resources, as appropriate, toward referring their patients to resources that might be able to help them resolve their HRSNs.

a. Background

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable.^{191,192,193,194,195} Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.^{196,197,198} Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community,

¹⁸⁷ Baker, M. C., Alberti, P. M., Tsao, T. Y., Fluegge, K., Howland, R. E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. *Health Affairs*, 40(4), 645–654. Available at: <https://doi.org/10.1377/hlthaff.2020.01742>.

¹⁸⁸ Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. *Circulation: Cardiovascular Quality and Outcomes*, 13 (6) 290-299. Available at: <https://doi.org/10.1161/CIRCOUTCOMES.120.006752>.

¹⁸⁹ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

¹⁹⁰ Jaffrey, J.B., Safran, G.B., Addressing Social Risk Factors in Value-Based Payment: Adjusting Payment Not Performance to Optimize Outcomes and Fairness. *Health Affairs Blog*, April 19, 2021. Available at: <https://www.healthaffairs.org/doi/10.1377/forefront.20210414.379479/full/>.

¹⁹¹ Seligman, H. K., & Berkowitz, S. A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. *Annual Review of Public Health*, 40(1), 319–337. Available at: <https://pubmed.ncbi.nlm.nih.gov/30444684/>.

¹⁹² The Physicians Foundation. 2020. Survey of America's Patients, Part Three. Available at: <https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf>.

¹⁹³ Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

¹⁹⁴ Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. *New England Journal of Medicine*. 2014; 371(24):2298–2308.

¹⁹⁵ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

¹⁹⁶ Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

¹⁹⁷ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

¹⁹⁸ Khullar, D., MD. 2020, September 8. Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at: https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/team-based-approach.pdf.

and environmental factors associated with health status and health outcomes.^{199,200,201} Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.^{202,203}

Significant and persistent health disparities in the United States result in adverse health outcomes for people with ESRD.^{204,205} The COVID-19 pandemic has illuminated the detrimental interaction between HRSNs, adverse health outcomes, and health care utilization in the United States.^{206,207} Emerging evidence has shown that specific social risk factors are directly associated with health outcomes and health care utilization and costs.^{208,209,210,211} Of particular concern

¹⁹⁹ Institute of Medicine. 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/18951>.

²⁰⁰ Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine* 374(1):8–11. Available at: <https://doi.org/10.1056/NEJMp1512532>.

²⁰¹ Centers for Disease Control and Prevention. CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html>. Accessed November 17, 2021.

²⁰² Zhang Y, Li J, Yu J, Braun RT, Casalino LP. 2021. Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*. 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

²⁰³ Khullar, D., Schpero, W. L., Bond, A. M., Qian, Y., & Casalino, L. P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*, 324(10), 975–983. <https://doi.org/10.1001/jama.2020.13129>.

²⁰⁴ United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

²⁰⁵ Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al. (2021). Initial Effects of COVID-19 on Patient with ESKD. *Journal of the American Society of Nephrology* 32: 1444-1453. doi: <https://doi.org/10.1681/ASN.2021010009>.

²⁰⁶ Centers for Disease Control. CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html>. Accessed November 17, 2021.

²⁰⁷ Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al. (2021). Initial Effects of COVID-19 on Patient with ESKD. *Journal of the American Society of Nephrology* 32: 1444-1453. doi: <https://doi.org/10.1681/ASN.2021010009>.

²⁰⁸ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053>.

²⁰⁹ Dean, E.B., French, M.T., Mortensen, K. (2020). *Health Services Research* 55 (Supplement 2): 883-893. doi: 10.1111/1475-6773.13283.

²¹⁰ Berkowitz, S.A., Kalkhoran, S., Edwards, S.T., Essien, U.R., Baggett, T.P. (2018). Unstable Housing and Diabetes-Related Emergency Department Visits and Hospitalization: A Nationally Representative Study of Safety-Net Clinic Patients. *Diabetes Care* 41: 933-939. <https://doi.org/10.2337/dc17-1812>.

²¹¹ National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25385>.

among people with ESRD are HRSNs that have an effect on treatment outcomes, including inadequate access to healthy foods, unstable housing, limited transportation, and community safety concerns.^{212,213}

We believe that improvement in care coordination between ESRD facilities, hospitals, and community-based organizations would yield better health outcomes for people with ESRD, and subsequently lead to improvements in quality performance for dialysis and other health care providers. We believe that the proposed Screening for Social Drivers of Health reporting measure would help inform facilities of the impact of HRSNs in people with ESRD by assessing the proportion of adult patients who are screened for social drivers of health in five core domains: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

In the CY 2023 ESRD PPS proposed rule, we sought public comment on the potential future inclusion of the Screening for Social Drivers of Health measure (87 FR 38554 through 38556) in the ESRD QIP. For a summary of the comments we received, as well as our responses, we refer readers to the CY 2023 ESRD PPS final rule (87 FR 67265 through 67268). In the CY 2023 ESRD PPS final rule, we stated that we were considering whether to incorporate measures that assess screening for health-related social needs into the ESRD QIP measure set (87 FR 67264).

We are proposing to adopt the Screening for Social Drivers of Health reporting measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP. As discussed above, disparities in health equity are tied to worse patient outcomes in the ESRD community. While widespread interest in addressing HRSNs exists, action is inconsistent, specifically in ESRD facilities. Therefore, we believe it is appropriate to require facilities to report data on this measure because the intent of the proposed

²¹² *Ibid.*

²¹³ CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: <https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf>.

measure is to incentivize facilities to collect and utilize their data to identify the impact of HRSNs in their ESRD patient population, including whether there is a relationship between those HRSNs and the outcomes experienced by their patients with those HRSNs. Screening data collected by the facility could inform their provision of care such that they improve the outcomes experienced by patients with HRSNs. Facilities could analyze their screening data to understand whether there are any HRSNs that may be affecting their patients' access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. While the measure does not require facilities to take specific actions following an HRSN screening, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the proposed measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a state's civil rights laws.

Under our Meaningful Measures Framework,²¹⁴ the Screening for Social Drivers of Health reporting measure, along with the Screen Positive Rate for Social Drivers of Health reporting measure discussed in section IV.D.3 of this proposed rule, addresses the quality priority of "Work with Communities to Promote Best Practices of Healthy Living" through the Meaningful Measures Area of "Equity of Care." Additionally, consistent with Meaningful Measures 2.0, these measures address the "healthcare equity" priority area and align with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to "develop and implement measures that reflect social and economic determinants."²¹⁵ Development and proposal of these measures also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health

²¹⁴ Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>.

²¹⁵ Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>. We note that Meaningful Measures 2.0 is still under development.

system.²¹⁶ We also believe these measures would address the quality priority “Promoting Effective Prevention and Treatment of Chronic Disease” through the Meaningful Measures Area “Management of Chronic Conditions,” by improving a facility’s ability to assess and implement effective care coordination for its patients. For example, data demonstrate that an overwhelming majority of people with ESRD travel outside their homes for dialysis three times per week, round trip, and that transportation challenges contribute to shortened treatment episodes and adverse health outcomes.^{217,218} Identification of patients with transportation difficulties could encourage facilities to provide information to these patients about available community-based transportation services that could help these patients with their transportation needs. We also believe that the proposed measures would encourage facilities to incorporate HRSN screening into their routine care, which would in turn improve their ability to understand the full needs of their patients, including those who may need additional care coordination but might be reluctant to otherwise seek assistance due to concerns about personal stigmatization.

Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.^{219,220} In 2017, CMS’s Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model to test the impact of systematically identifying and addressing the HRSNs of community-dwelling Medicare and Medicaid beneficiaries (through screening, referral, and community navigation on

²¹⁶ Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: <https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms>.

²¹⁷ *Ibid.*

²¹⁸ United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

²¹⁹ Zhang Y, Li J, Yu J, Braun RT, Casalino LP. 2021. Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*. 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

²²⁰ Khullar, D., Schpero, W. L., Bond, A. M., Qian, Y., & Casalino, L. P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*, 324(10), 975–983. <https://doi.org/10.1001/jama.2020.13129>.

their health outcomes and related healthcare utilization and costs).^{221,222,223,224} The CMS Innovation Center developed the AHC Model based on evidence that addressing HRSNs through enhanced linkages between health systems and community-based organizations can improve health outcomes and reduce costs.²²⁵ HRSNs are significant risk factors associated with adverse health outcomes and increased health care utilization, including excessive emergency department (ED) visits and avoidable hospitalizations.^{226,227} Unmet HRSNs, such as food insecurity, inadequate or unstable housing, and inadequate transportation may increase risk for onset of chronic conditions, such as ESRD, and accelerate exacerbation of related adverse health outcomes.^{228,229,230} The AHC Model had a 5-year period of performance that began in May 2017 and concluded in April 2022, with beneficiary screening beginning in the summer of 2018 following an implementation period.^{231,232} Evaluation of the AHC Model data is still underway,

²²¹ Centers for Medicare & Medicaid Services. 2021. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>.

²²² Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine* 374(1):8–11. Available at: <https://doi.org/10.1056/NEJMp1512532>.

²²³ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²²⁴ Centers for Medicare & Medicaid Services. 2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: <https://innovation.cms.gov/innovation-models/ahcm>.

²²⁵ RTI International. 2020. Accountable Health Communities (AHC) Model Evaluation. Available at: <https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt>.

²²⁶ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²²⁷ Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine* 374(1):8–11. Available at: <https://doi.org/10.1056/NEJMp1512532>.

²²⁸ Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

²²⁹ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053>.

²³⁰ Laraia, B.A. (2013). Food Insecurity and Chronic Disease. *Advances in Nutrition*, 4: 203-212, doi: 10.3945/an.112.003277.

²³¹ RTI International. 2020. Accountable Health Communities (AHC) Model Evaluation. Available at: <https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt>.

²³² We note that the model officially concluded in April 2022 but many awardees are continuing with no-cost extensions to continue utilizing unspent cooperative agreement funding and all awardees will conclude by April 2023.

and the most recent evaluation was published in the second AHC Model evaluation report on May 18, 2023.²³³

While social risk factors may have a significant impact on health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.^{234,235,236,237} The persistent interactions between individuals' HRSNs, medical providers' practices/behaviors, and community resources significantly impact healthcare access, quality, and ultimately costs, as described in the CMS Equity Plan for Improving Quality in Medicare.^{238,239} In their 2018 survey of 8,500 physicians, The Physicians Foundation found almost 90 percent of physician respondents reported their patients had a serious health problem linked to poverty or other social conditions.²⁴⁰ Additionally, associations between disproportionate health risk, hospitalization,

²³³ RTI International. 2023. Accountable Health Communities (AHC) Model Evaluation. Available at: <https://innovation.cms.gov/data-and-reports/2023/ahc-second-eval-rpt>.

²³⁴ Kaiser Family Foundation. 2021. Racial and Ethnic Health Inequities and Medicare. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>. Accessed November 23, 2021.

²³⁵ Khullar, D., MD. 2020, September 8. Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. 2020. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity.

²³⁶ Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. *Circulation: Cardiovascular Quality and Outcomes*, 13 (6) 290-299. Available at: <https://doi.org/10.1161/CIRCOUTCOMES.120.006752>.

²³⁷ The Physicians Foundation. 2021. Viewpoints: Social Determinants of Health. Available at: <https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf>. Accessed December 8, 2021.

²³⁸ Centers for Medicare & Medicaid Services. 2021. Paving the Way to Equity: A Progress Report. Accessed January 18, 2022. Available at: <https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>.

²³⁹ Centers for Medicare & Medicaid Services Office of Minority Health. 2021. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input.

²⁴⁰ The Physicians Foundation. 2019. Viewpoints: Social Determinants of Health. Available at: <https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf>. Accessed December 8, 2021.

and adverse health outcomes have been highlighted and magnified by the COVID-19 pandemic.^{241,242}

The following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries under the AHC Model: 1) food insecurity; 2) housing instability; 3) transportation needs; 4) utility difficulties; and 5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria: 1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs; 2) ability for a given HRSN to be screened and identified in the inpatient setting prior to hospital discharge, addressed by community-based services, and potentially improve healthcare outcomes, including reduced hospital re-admissions; and 3) evidence that a given HRSN is not systematically addressed by healthcare providers.²⁴³ In addition to established evidence of their association with health status, risk, and outcomes, these five domains were also selected because they can be assessed across the broadest spectrum of individuals in a variety of settings.^{244,245,246}

These five evidence-based HRSN domains informed our development of the proposed Screening for Social Drivers of Health reporting measure, as well as a second measure, Screen

²⁴¹ Centers for Disease Control and Prevention. 2020. CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html>. Accessed November 17, 2021.

²⁴² Kaiser Family Foundation. 2021. Racial and Ethnic Health Inequities and Medicare. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>. Accessed November 23, 2021.

²⁴³ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²⁴⁴ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²⁴⁵ Centers for Medicare & Medicaid Services. 2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: <https://innovation.cms.gov/innovation-models/ahcm>.

²⁴⁶ Kamyck, D., Senior Director of Marketing. 2019. CMS releases standardized screening tool for health-related social needs. Activate Care. Available at: <https://blog.activatecare.com/standardized-screening-for-health-related-social-needs-in-clinical-settings-the-accountable-health-communities-screening-tool/>.

Positive Rate for Social Drivers of Health reporting measure, that we are also proposing to adopt for the ESRD QIP. These domains are described in Table 21.

TABLE 21: Five Core HRSN Domains Used in the Screening for Social Drivers of Health Reporting Measure and the Screen Positive Rate for Social Drivers of Health Reporting Measure

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions. ^{247,248} Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health services. ^{249,250} Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and hospitalizations. ^{251,252,253}
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence. ^{254,255} Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing unstable housing. ²⁵⁶ Housing

²⁴⁷ Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. *Am J Managed Care*. 2018 Sep;24(9):399-404. PMID: 30222918; PMCID: PMC6426124.

²⁴⁸ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

²⁴⁹ Seligman, H. K. & Berkowitz, S. A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. *Annual Review of Public Health*, 40(1), 319–337. Available at: <https://pubmed.ncbi.nlm.nih.gov/30444684/>.

²⁵⁰ National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/23285>.

²⁵¹ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

²⁵² Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. *Am J Managed Care*. 2018 Sep;24(9):399-404. PMID: 30222918; PMCID: PMC6426124.

²⁵³ Dean, E. B., French, M. T., & Mortensen, K. (2020a). Food insecurity, health care utilization, and health care expenditures. *Health Services Research*, 55(S2), 883–893. Available at: <https://doi.org/10.1111/1475-6773.13283>.

²⁵⁴ Larimer, M. E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. *JAMA*, 301(13), 1349. Available at: <https://doi.org/10.1001/jama.2009.414>.

²⁵⁵ Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

²⁵⁶ Henry, M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: <https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf>.

Domain	Description
	instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services. ^{257,258}
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living. ²⁵⁹ Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and more frequent utilization of high-cost healthcare services including emergency medical services, EDs, and hospitalizations. ^{260,261,262,263}
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity. ²⁶⁴ Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements. ²⁶⁵
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse. ²⁶⁶ Exposure to violence and social isolation are reflective of individual-level social

²⁵⁷ Larimer, M. E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. *JAMA*, 301(13), 1349. Available at: <https://doi.org/10.1001/jama.2009.414>.

²⁵⁸ Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health*, 73; 379 – 387. Available at: <https://jech.bmj.com/content/jech/73/5/379.full.pdf>.

²⁵⁹ National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/23285>.

²⁶⁰ National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/23285>.

²⁶¹ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

²⁶² Billieux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²⁶³ Shier, G., Ginsburg, M., Howell, J., Volland, P., & Golden, R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. *Health Affairs*, 32(3), 544–551. Available at: <https://doi.org/10.1377/hlthaff.2012.0170>.

²⁶⁴ Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health*, 73; 379 – 387. Available at: <https://jech.bmj.com/content/jech/73/5/379.full.pdf>.

²⁶⁵ Wright, B. J., Vartanian, K. B., Li, H. F., Royal, N., & Matson, J. K. (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. *Health Affairs*, 35(1), 20–27. Available at: <https://doi.org/10.1377/hlthaff.2015.0393>.

²⁶⁶ Billieux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

Domain**Description**

relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups.^{267,268}

The proposed Screening for Social Drivers of Health reporting measure assesses screening of the same HRSNs.

We are proposing that facilities would be able to choose a screening tool for purposes of this measure or otherwise screen their patients using a method of their choosing in order to give facilities the flexibility to accommodate the population they serve and their individual needs.^{269,270} We note that the 10-item AHC Health-Related Social Needs Screening Tool that AHC Model participants used to identify HRSNs in the five core domains (described in Table 21) among community-dwelling Medicare, Medicaid, and dually eligible beneficiaries was tested across varied care-delivery sites in diverse geographic locations across the U.S.^{271,272} Facilities may wish to consider using that tool because it has been found to be both reliable and valid, including high inter-rater reliability and concurrent and predictive validity.²⁷³ Moreover, the screening tool can be implemented in a variety of places where patients seek healthcare, including dialysis facilities.²⁷⁴ However, as stated above, we are not proposing to require facilities to use this tool,

²⁶⁷ Henry, M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: <https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf>.

²⁶⁸ Larimer, M. E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. *JAMA*, 301(13), 1349. Available at: <https://doi.org/10.1001/jama.2009.414>.

²⁶⁹ Social Interventions Research & Evaluation Network. 2019. Social Needs Screening Tool Comparison Table. Available at: <https://sirennetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison>. Accessed January 18, 2021.

²⁷⁰ Centers for Medicare & Medicaid Services. 2021. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>. Accessed January 18, 2021.

²⁷¹ More information on the HRSN Screening Tool is available at: <https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf>.

²⁷² RTI International. 2020. Accountable Health Communities (AHC) Model Evaluation. Available at: <https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt>.

²⁷³ Lewis C., Wellman R., Jones S., Walsh-Bailey C., Thompson E., Derus A., Paolino A., Steiner J., De Marchis E., Gottlieb L., and Sharp A. (2020). Comparing the Performance of Two Social Risk Screening Tools in a Vulnerable Subpopulation. *J Family Med Prim Care*. 2020 Sep; 9(9): 5026–5034. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/>.

²⁷⁴ CMS. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>.

or any other specific tool, for purposes of the proposed Screening for Social Drivers of Health reporting measure.

b. Overview of Measure

The Screening for Social Drivers of Health measure would assess the percentage of patients age 18 and older that a dialysis facility screens for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. To report on this measure, facilities would provide: (1) the number of patients admitted to the facility who are 18 years or older during the applicable performance period who are screened for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety; and (2) the total number of patients at the facility who are 18 years or older during the applicable performance period and who are not excluded from the measure. We are proposing to add this measure to the Reporting Measure Domain beginning with PY 2027. We discuss our proposed updates to measure domains and weights for PY 2027 in section IV.D.7 of this proposed rule.

Measure specifications for this proposed measure are currently available on the QualityNet website at: <https://qualitynet.cms.gov/esrd/esrdqip>.

(1) Cohort

The cohort for the proposed Screening for Social Drivers of Health reporting measure is all patients, aged 18 years and older, who are treated at the facility during the applicable performance period and not eligible to be excluded from the measure.

(2) Numerator

The numerator is calculated as the number of patients who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened during the performance period for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

(3) Denominator

The denominator is calculated as the number of patients at the dialysis facility and who are 18 years or older on the first day of the performance period. The following patients would be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are unable to complete the screening and have no legal guardian or caregiver who is able to complete the screening on their behalf.

c. Measure Calculation

The Screening for Social Drivers of Health measure would be calculated as the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened by the facility for all five HSRNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the total number of patients 18 years or older on the 1st day of the performance period (January 1st) at that dialysis facility. We are proposing a 12-month period of performance for the measure, and facilities would be required to report annually. We are proposing that a facility would be scored according to the following equation:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Screened for all Five HSRNs During the Performance Period}}{\text{Total Number of Eligible Patients During the Performance Period}} \right] \times 10$$

We believe that this scoring policy would encourage facilities to report the measure data appropriately without penalizing facilities for the results of such data, which may be based on circumstances beyond a facility's control.

d. Data Submission and Reporting

We are proposing that facilities would report this measure on an annual basis beginning with PY 2027. In alignment with the policy we finalized for the Hospital IQR Program, we are proposing that facilities would be able to select their own screening tool or method to screen patients for food insecurity, housing instability, transportation needs, utility difficulties, and

interpersonal safety. Potential sources of these data for incorporation in a tool could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys. Additionally, multiple screening tools exist and are publicly available. Facilities could refer to the Social Interventions Research and Evaluation Network (SIREN) website, for example, for comprehensive information about the most widely used HRSN screening tools.^{275,276} SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions. We would encourage facilities to consider digital standardized screening tools and refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207), where we noted that the use of certified health IT can support capture of HRSN information in an interoperable fashion so that these data can be shared across the care continuum to support coordinated care.

We are proposing that the deadline for submission would be the end of the EQRS December data reporting month for the applicable performance period, which is consistent with current reporting deadlines for other ESRD QIP measures. For example, the deadline for submission in PY 2027 would be the end of the December data reporting month in CY 2025.

e. Review by the Measure Applications Partnership

We included the Screening for Social Drivers of Health reporting measure as a measure under consideration for the ESRD QIP on the publicly available 2022 MUC List, a list of measures under consideration for use in various Medicare programs.²⁷⁷ The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List and the Screening for Social Drivers of Health measure (MUC 2022–053) in detail and at the same time as the Screen Positive

²⁷⁵ Social Interventions Research & Evaluation Network. 2019. Social Needs Screening Tool Comparison Table. Available at: <https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison>. Accessed January 18, 2021.

²⁷⁶ The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on the social determinants of health and healthcare delivery.

²⁷⁷ Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. Available at: <https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx>.

Rate for Social Drivers of Health measure on December 6-7, 2022 (discussed below).²⁷⁸ The Health Equity Advisory Group expressed support for the data collection related to social drivers of health, but raised concerns about public reporting of the data and redundancy in asking for the same information of patients. In addition, on December 8-9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and the MAP Hospital Workgroup did so on December 13-14, 2022.²⁷⁹ The Rural Health Advisory Group noted some potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but expressed that the measure serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue. The MAP Hospital Workgroup members conditionally supported the measure pending: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.²⁸⁰ Thereafter, the MAP Coordinating Committee deliberated on January 24-25, 2023, and ultimately voted to conditionally support the Screening for Social Drivers of Health reporting measure for rulemaking with the same conditions.²⁸¹

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section

²⁷⁸ Centers for Medicare & Medicaid Services. 2022. 2022-2023 MAP Preliminary Recommendations. Health Equity Advisory Group. Available at: <https://www.qualityforum.org/ProjectMaterials.aspx?projectID=95514>.

²⁷⁹ Centers for Medicare & Medicaid Services. 2022. 2022-2023 MAP Preliminary Recommendations, Rural Health Advisory Group. Available at: https://www.qualityforum.org/MAP_Rural_Health_Advisory_Group.aspx and MAP Hospital Workgroup. Available at: https://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx

²⁸⁰ Centers for Medicare & Medicaid Services. (2022). 2022-2023 MAP Final Recommendations. Available at <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=98102>. For Information on the GRAVITY project, please see <https://thegravityproject.net/>.

²⁸¹ Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

We are proposing to publicly display the facility-specific results for the Screening for Social Drivers of Health measure on an annual basis through our *Care Compare* website at: <https://www.medicare.gov/care-compare/>. We anticipate making the first public report available in January 2027.

We invite public comment on this proposal.

3. Proposal to Adopt the Screen Positive Rate for Social Drivers of Health Reporting Measure Beginning with PY 2027

a. Background

The impact of social risk factors on health outcomes has been well-established in the literature.^{282,283,284,285,286} The Physicians Foundation reported that 73 percent of the physician respondents to their annual survey agreed that social risk factors such as housing instability and food insecurity would drive health services demand in 2021.²⁸⁷ Recognizing the need for a more comprehensive approach to closing equity gaps, we have prioritized quality measures that identify social drivers of health among patients served in various care settings and, in turn, support providers in addressing the impact of these drivers on disparities in patient outcomes, healthcare utilization, and costs.^{288,289,290} Specifically, in the dialysis facility setting, we aim to encourage systematic identification of patients' HRSNs as part of treatment planning, with the intention of promoting linkages with relevant community-based services that address those needs. We also believe that the identification of HRSNs can help facilities devise strategies that

²⁸² Institute of Medicine 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/18951>.

²⁸³ Centers for Medicare & Medicaid Services. 2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: <https://innovation.cms.gov/innovation-models/ahcm>. Accessed November 23, 2021.

²⁸⁴ Kaiser Family Foundation. 2021. Racial and Ethnic Health Inequities and Medicare. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>. Accessed November 23, 2021.

²⁸⁵ Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, *Journal of Women's Health* 26(6) (2016) at 58; Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. *Health Psychology*, 35(4), 351–355. <https://doi.org/10.1037/hea0000268>.

²⁸⁶ Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2020. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

²⁸⁷ The Physicians Foundation. (2020) 2020 Survey of America's Patients, Part Three. Available at: <https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf>.

²⁸⁸ Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine* 374(1):8–11. Available at: <https://doi.org/10.1056/NEJMp1512532>.

²⁸⁹ Centers for Medicare & Medicaid Services. 2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: <https://innovation.cms.gov/innovation-models/ahcm>. Accessed November 23, 2021.

²⁹⁰ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

improve the quality of care provided to all of their patients and lead to improved health outcomes following establishment of care at the facility.

While the proposed Screening for Social Drivers of Health reporting measure (discussed in section IV.D.2 of this proposed rule) enables facilities to identify patients with HRSNs, the Screen Positive Rate for Social Drivers of Health measure would allow facilities to capture the magnitude of these needs by reporting the rate of those patients who screen positive for HRSNs and even potentially estimate the impact of individual-level HRSNs on healthcare utilization when evaluating quality of care.^{291,292,293} These measures complement each other because they would require facilities to report both the percentage of patients they screened (under the proposed Screening for Social Drivers of Health measure) and the results of that screening (under the proposed Screen Positive Rate for Social Drivers of Health measure) in order to potentially identify gaps and develop sustainable solutions at a facility level and a community level. We note that our proposals to adopt these two separate, complementary measures align with other quality reporting programs. These two measures have been finalized for the Hospital Inpatient Quality Reporting Program in the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital Prospective Payment System (LTCH PPS) final rule (87 FR 49191 through 49220), and are currently proposed for the PPS-Exempt Cancer Hospital Quality Reporting Program in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27122 through 27130) and the Inpatient Psychiatric Facility Quality Reporting Program in the FY 2024 IPF PPS proposed rule (88 FR 21279 through 21288).

²⁹¹ Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. *Health Affairs*, 40(4), 645–654. Available at: <https://doi.org/10.1377/hlthaff.2020.01742>.

²⁹² CMS. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: <https://innovation.cms.gov/innovation-models/ahcm>. Accessed November 23, 2021.

²⁹³ Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. *Circulation: Cardiovascular Quality and Outcomes*, 13 (6) 290–299. Available at: <https://doi.org/10.1161/CIRCOUTCOMES.120.006752>.

We are proposing to adopt this proposed measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP. The Screen Positive Rate for Social Drivers of Health reporting measure would require facilities to screen all patients who are 18 years or older for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety and then report the resulting screen positive rates for each of those domains to CMS. These are the same five core HRSN domains that facilities would be required to screen for under the proposed Screening for Social Drivers of Health reporting measure, and facilities could use the same screening tool for purposes of both measures. Reporting the screen positive rate for social drivers of health for each domain could inform actionable planning by facilities by helping to enable the development of individual patient action plans for those patients who screen positive (including navigation and referral). Following a positive HRSN screening, facilities could analyze data to understand, for example, whether there are any HRSNs that may be affecting their patients' access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. Thus, this measure has the potential to improve patient outcomes by acknowledging patients' non-clinical needs that nevertheless greatly contribute to adverse clinical outcomes and providing the opportunity for additional support by linking providers with community-based organizations to enhance patient-centered treatment and discharge planning, although such reach out is not required.^{294,295,296} This measure may also prove useful to patients by providing data transparency and signifying facilities' familiarity, expertise, and commitment regarding these issues. Finally, we believe this measure has the potential to facilitate data-informed collaboration with community-based services and focused community

²⁹⁴ The Physicians Foundation. 2020. Survey of America's Patients, Part Three. Available at: <https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf>.

²⁹⁵ De Marchis, E., Knox, M., Hessler, D., Willard-Grace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. *The Journal of the American Board of Family Medicine*, 32 (1), 69 through 78.

²⁹⁶ Kung, A., Cheung, T., Knox, M., Willard-Grace, R., Halpern, J., et al. (2019). Capacity to Address Social Needs Affect Primary Care Clinician Burnout. *Annals of Family Medicine*. 17 (6), 487 through 494. Available at: <https://doi.org/10.1370/afm.2470>.

investments, including the development of pathways and infrastructure to more seamlessly connect patients to local community resources. Thus, the measure aims to support facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources. While the measure does not require facilities to take specific actions, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the proposed measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a state's civil rights laws.

b. Overview of Measure

The Screen Positive Rate for Social Drivers of Health measure would identify the proportion of patients at the facility who screened positive for each of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. We would require facilities to report these data as five separate rates.²⁹⁷ We refer readers to section IV.D.2 of this proposed rule where we discussed our process for identifying these five domains, which we are also proposing to use for the proposed Screening for Social Drivers of Health reporting measure.

Measure specifications for this measure are currently available on the QualityNet website at: <https://qualitynet.cms.gov/esrd/esrdqip>.

(1) Cohort

The cohort for the Screen Positive Rate for Social Drivers of Health is a process measure that would provide information on the percentage of patients, aged 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened by the facility for an HRSN, and who screened

²⁹⁷ Billieux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety.

(2) Numerator

The numerator would consist of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened for an HRSN, and for whom the facility reports the results of a screen asking whether they have a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.

(3) Denominator

The denominator would consist of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened for an HRSN (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety). The following patients would be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening and have no caregiver able to do so on the patient's behalf.

c. Measure Calculation

The facility's measure rate for this measure would be calculated for a payment year as the number of eligible patients for whom the facility reports the screening results for all five HRSNs during the performance period over the total number of eligible patients who the facility screened for all five HRSNs during that performance period. To calculate the facility's score on the measure, we would multiply the results of that fraction by ten. The full equation is set forth here:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Reports Screening Results for all Five HSRNs During the Performance Period}}{\text{Total Number of Eligible Patients who were Screened for all Five HSRNs During the Performance Period}} \right] \times 10$$

However, for purposes of public reporting only, we are proposing to display the facility's screen positive rate for each HRSN separately, for a total of five separate rates. Although we will not score facilities on the results of those five separate rates, we believe that making such data public may help to better inform patients and their caregivers about a facility. We are proposing a 12-month period of performance for the measure, and facilities would be required to report annually.

We believe that these policies would encourage facilities to report the measure data appropriately without scoring facilities based on the results of such data, which may be based on circumstances beyond a facility's control. Although we believe that it is important to encourage facilities to screen their patients for HSRNs and to report data for screen positive rates, we want to avoid potential unintended consequences that may result from scoring facilities on the outcomes of the screen positive rates themselves. That is, we do not want to score a facility based on its patients' given socioeconomic factors, which may be based on circumstances beyond a facility's control.

d. Data Collection, Submission and Reporting

We are proposing that facilities would be required to submit data necessary to calculate the numerator and the denominator for this measure once annually within the ESRD Quality Reporting System (EQRS), beginning with PY 2027. We are proposing that facilities would be required to submit data on this proposed measure using the same process we have finalized for the submission of data on other measures in the ESRD QIP within EQRS.

e. Review by the Measure Applications Partnership

We included the Screen Positive Rate for Social Drivers of Health reporting measure for consideration in the ESRD QIP on the publicly available 2022 MUC List, a list of measures under consideration for use in various Medicare programs.²⁹⁸ The CBE-convened MAP Health

²⁹⁸ Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. Available at: <https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx>.

Equity Advisory Group reviewed the Screen Positive Rate for Social Drivers of Health measure (MUC 2022–050) in detail and at the same time as the Screening for Social Drivers of Health measure on December 6-7, 2022.²⁹⁹ The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting and the repetition of asking patients the same questions. In addition, on December 8-9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and was also reviewed by the MAP Hospital Workgroup on December 13-14, 2022.³⁰⁰ The Rural Health Advisory Group noted potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but also expressed support that the measure seeks to advance the drivers of health and serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup recommended conditional support for the measure for rulemaking pending endorsement by a CBE to address reliability and validity concerns, attentiveness to how results are shared and contextualized for public reporting, and encouragement for CMS to examine any differences in reported rates by reporting process (to assess whether they are the same or different across dialysis facilities).³⁰¹ Thereafter, the MAP Coordinating Committee deliberated on January 24-25, 2023, and ultimately voted to conditionally support the Screen Positive Rate for Social Drivers of Health measure for rulemaking with the same conditions.³⁰²

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section

²⁹⁹ Centers for Medicare & Medicaid Services. 2022. 2022-2023 MAP Preliminary Recommendations, Health Equity Advisory Group. Available at: <https://www.qualityforum.org/ProjectMaterials.aspx?projectID=95514>.

³⁰⁰ Centers for Medicare & Medicaid Services. 2022. MAP Preliminary Recommendations, Rural Health Advisory Group. Available at https://www.qualityforum.org/MAP_Rural_Health_Advisory_Group.aspx; See also, MAP Hospital Workgroup. Available at: https://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

³⁰¹ Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

³⁰² Centers for Medicare & Medicaid Services. 2023. 2022-2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

We are proposing to publicly display the ESRD QIP score and facility-specific rates for the Screen Positive Rate for Social Drivers of Health measure on an annual basis beginning in PY 2027 through our *Care Compare* website at: <https://www.medicare.gov/care-compare/>.

We invite public comment on this proposal.

4. Performance Period for the PY 2027 ESRD QIP

We continue to believe that our current policy of 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt CY 2025 as the performance period and CY 2023 as the baseline period for the PY 2027 ESRD QIP.

We are not proposing any changes to this policy.

5. Performance Standards for the PY 2027 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a

discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively. For reporting measures, performance standards are the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure (42 CFR 413.178(a)(12)).

a. Performance Standards for Clinical Measures in the PY 2027 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we do not have CY 2022 data. We intend to publish these numerical values, using CY 2022 data, in the CY 2024 ESRD PPS final rule.

b. Proposed Performance Standards for the Newly Proposed Reporting Measures Beginning with the PY 2027 ESRD QIP

We are proposing to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with the PY 2027 ESRD QIP, which we discuss in IV.D.2 and IV.D.3 of this proposed rule. We are proposing a 12-month period of performance for both the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure, and facilities would be required to report annually for both measures beginning with the PY 2027 ESRD QIP.

6. Scoring the PY 2027 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at

42 CFR 413.178(e). In the CY 2023 ESRD PPS final rule, we updated our scoring methodology beginning with PY 2025 (87 FR 67251 through 67254).

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at 42 CFR 413.178(e). In section IV.D.2 of this proposed rule, we are proposing to adopt the Screening for Social Drivers of Health reporting measure beginning with PY 2027. We are also proposing to adopt the Screen Positive Rate for Social Drivers of Health reporting measure, as discussed in section IV.D.3 of this proposed rule. We are proposing that a facility would be scored based on the equations proposed in sections IV.D.2.c and IV.D.3.c of this proposed rule. We are proposing a 12-month period of performance for the measures, and facilities would be required to report annually. We believe that these scoring policies would encourage facilities to report the measure data appropriately without penalizing facilities for the results of such data, which may be impacted by circumstances beyond a facility's control.

7. Proposed Revisions to Measure Domains and to Measure Weights Used to Calculate the Total Performance Score (TPS) Beginning with the PY 2027 ESRD QIP

Beginning with PY 2027, we are proposing to add the Screening for Social Drivers of Health reporting measure and the Screen Positive for Social Drivers of Health reporting measure to the Reporting Measure Domain. To accommodate the new number of measures in the Reporting Measure Domain, we are proposing to update the individual measure weights in this domain. We believe that these proposed updates would help to ensure that a facility's individual measure performance has an appropriately proportionate impact on a facility's TPS, while also continuing to further incentivize improvement on clinical measures through those individual measure weights. Consistent with our approach in the CY 2023 ESRD PPS final rule, we are proposing to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure Domain so that each measure is weighted equally (87 FR 67251 through 67253). Since we are adding two new measures to the Reporting Measure

Domain beginning with PY 2027, we would weight each measure within that domain equally at approximately 1.43, which is consistent with our previously finalized approach to weight each measure in the Reporting Measure Domain equally. We note that although we are proposing to change the number of measures in the Reporting Measure Domain and weights of certain individual measures in that domain, we are not proposing to change the weights of the five domains themselves, because we believe the proposed updates to individual measures and measure weights do not significantly impact the measure domains themselves such that updating the weights of the measure domains would be required to accommodate the updated individual measure weights. The previously finalized and newly proposed measures that would be included in each domain, along with the proposed new measure weights, beginning with PY 2027 are depicted in Table 22.

TABLE 22: Proposed ESRD QIP Measure Domains and Weights Beginning with PY 2027

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure**	7.50
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure	10.00
Reporting Measure Domain	10.00
Screening for Social Drivers of Health measure*	1.43
Screen Positive Rate for Social Drivers of Health reporting measure****	1.43
Facility Commitment to Health Equity reporting measure****	1.43
Hypercalcemia reporting measure	1.43
MedRec reporting measure	1.43
NHSN Dialysis Event reporting measure	1.43
COVID-19 HCP Vaccination reporting measure	1.43

*We are proposing to add the Screening for Social Drivers of Health measure beginning with PY 2027, as discussed in section IV.D.2 of this proposed rule.

******We are proposing to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

*******We are proposing to add the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.3 of this proposed rule.

********We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

We welcome public comment on these proposals.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support Beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas – a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to

be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codesTM located in Maryland.³⁰³ CMS excludes all U.S. Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDP), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDP applies to claims with claim service dates beginning January 1, 2021 and ending December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period – a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we would make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022 and ending June 30, 2027.

In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We made adjustments to the calculation of the home dialysis rate

³⁰³ ZIP codeTM is a trademark of the United States Postal Service.

(86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive Living Donor Transplant (LDT) Beneficiaries (86 FR 61950 through 61951). We modified the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994). In the CY 2023 ESRD PPS final rule (87 FR 67136) we finalized further changes to the ETC Model. We updated the PPA achievement scoring methodology beginning in the fifth Measurement Year (MY) of the ETC Model, which began on January 1, 2023 (87 FR 67277 through 67278). We also clarified requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers (87 FR 67278 through 67280), and finalized our intent to publish participant-level model performance information to the public (87 FR 67280).

B. Summary of the Proposed Provisions to the ETC Model

In the Specialty Care Models final rule (85 FR 61114), we established our policies for targeted reviews of the calculation of an ETC Participant's Modality Performance Score (MPS). As described in § 512.390(c), targeted reviews are limited to the calculation of the MPS and may not pertain to the methodologies used to calculate the MPS, home dialysis rate, transplant rates, achievement and improvement benchmarks, or the PPA amounts. ETC Participants have 90 days following the availability of the MPS to submit a targeted review request. CMS responds to each targeted review request that is received within the 90-day time period. CMS may solicit additional information from the ETC Participant in support of the request after which a determination is made as to whether there was an error in the calculation of the ETC Participant's MPS that results in an incorrect PPA being applied during the PPA period. In such

a scenario, CMS notifies the ETC Participant and resolves any resulting discrepancy in payment that arises from the application of an incorrect PPA.

We are proposing revisions to our regulations at § 512.390 to clarify the ability of the CMS Administrator to review targeted review determinations. In particular, we are proposing to add § 512.390(d) to specify that the CMS Administrator may review targeted review requests when administrative review is requested by ETC Participants within 15-calendar days of a targeted review request determination made by CMS.

We are proposing that within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows: (i) decline to review the targeted review request determination made by CMS, (ii) render a final decision based on the CMS Administrator's review of the targeted review request determination, or (iii) choose to take no action on the request for administrative review. We are proposing that targeted review request determinations made by the CMS Administrator are considered final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period described.

We are also proposing a conforming change to delete the existing provision in § 512.390(c)(5), which states that decisions based on targeted review are final, and there is no further review or appeal.

These proposed changes would ensure that accountability for the decisions of CMS is vested in a principal officer and would bring the targeted review process to a more similar posture as other CMS appeals entities that provide for CMS Administrator review. These proposed revisions would also ensure that ETC Participants are aware that administrative review is available to ETC Participants who wish to seek additional review of the results of a targeted review request.

We seek comment on this proposal.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues.

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Regarding the Proposed JW and JZ Reporting Requirements; Proposed Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS, Section II.B.1.h (OMB control number 0938-0997)

As discussed in section II.B.1.h of this proposed rule, we are proposing to require that beginning January 1, 2024, ESRD facilities must report information on claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). Additionally, we are proposing to require ESRD facilities to report the JZ modifier for all such drugs and biological products with no discarded amounts beginning no later than January 1, 2024. Based on our analysis of ESRD PPS claims as well as the billing guidance in sections 8 and 17 of the Medicare

Claims Processing Manual, we have determined that the proposed JW modifier requirement reflects current practices for ESRD facilities, and would not significantly increase burden for ESRD facilities. Additionally, the proposed JZ modifier requirement is not expected to increase burden on ESRD facilities because under the guidance provided regarding use of the JW modifier, the ESRD facility should already have processes in place in order to determine, in the case of certain drugs and biological products, whether or not there are any discarded units from a single use container or package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. Additionally, as discussed in section II.B.1.h of this proposed rule, any separately payable drugs or biological products that ESRD facilities bill for using the AY modifier would already be subject to the JW and JZ modifier policies under Medicare Part B. Therefore, most ESRD facilities should already be set up to report the JW and JZ modifiers in such circumstances, and would reasonably be able to report these modifiers for renal dialysis drugs and biological products as well.

B. ICRs Regarding the Proposal to Require Time on Machine Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis; Section II.B.1.j (OMB control numbers 0938-0997)

We are proposing to require ESRD facilities to submit data and information on ESRD PPS claims regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use involved (that is, reporting on ESRD PPS patient claims the minutes of time on machine for each hemodialysis treatment) in furnishing renal dialysis services at ESRD facilities. We have developed monetary estimates of the amount of ESRD facility staff time required to report this information on claims in order to estimate the costs associated with the proposal to require the reporting of time on machine data. We have included those estimates in the Regulatory Impact Analysis section of this proposed rule. We acknowledge the burden associated with this proposed requirement, but

we note that the burden associated with the CMS-1450 institutional claim form already accounts for the variability in the number and type of codes submitted for each claim.

C. Additional Information Collection Requirements

1. ESRD QIP - Wage Estimates (OMB control numbers 0938-1289 and 0938-1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the CDC's National Healthcare Safety Network (NHSN), as well as compiling and submitting patient records for the purpose of data validation studies. The most recently available median hourly wage of a Medical Records Specialist is \$22.43 per hour.³⁰⁴ We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Therefore, using these assumptions, we estimated an hourly labor cost of \$44.86 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this updated wage estimate, along with updated facility and patient counts, to update our estimate for the total information collection burden in the ESRD QIP for PY 2026 that we discussed in the CY 2023 ESRD PPS final rule (87 FR 67281) and to estimate the total

³⁰⁴ <https://www.bls.gov/oes/current/oes292072.htm>. Accessed on January 3, 2023.

information collection burden in the ESRD QIP for PY 2027, which we discuss further in section VIII.C.3 of this proposed rule.

2. Estimated Burden Associated with the Data Validation Requirements for PY 2026 and PY 2027 (OMB control numbers 0938-1289 and 0938-1340)

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the EQRS (formerly, CROWNWeb) data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate EQRS data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In this proposed rule, we are updating these burden estimates using a newly available wage estimate of a Medical Records Specialist. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement (84 FR 60787). If 300 facilities are requested to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities x 2.5 hours). Since we anticipate that Medical Records Specialists or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately \$33,645 (750 hours x \$44.86), or an annual total of approximately \$112.15 (\$33,645 / 300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938-1289; Expiration date: November 30, 2025).

In the CY 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead

of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. Applying this policy for NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are requested to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities x 5 hours). Since we anticipate that Medical Records Specialists or similar staff would submit these data, using the newly available wage estimate of a Medical Records Specialist, we estimate that the aggregate cost of the NHSN data validation each year would be approximately \$67,290 (1,500 hours × \$44.86), or a total of approximately \$224.30 (\$67,290/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938-1340; Expiration date: November 30, 2025).

3. Estimated EQRS Reporting Requirements for PY 2026 and PY 2027 (OMB control number 0938-1289)

To estimate the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2023 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2026 ESRD QIP was approximately \$220 million for approximately 4,908,291 total burden hours (87 FR 67282).

We are proposing several changes to the ESRD QIP measure set in this proposed rule that would affect the burden associated with EQRS reporting requirements for PY 2026 or PY 2027.

Beginning with PY 2026, we are proposing to remove two measures from the ESRD QIP measure set and to add one measure to the ESRD QIP measure set. For PY 2027 and for subsequent years, we are proposing to add two measures to the ESRD QIP measure set. We have re-calculated the burden estimate for PY 2026 to reflect the impact of these proposals if finalized, using updated estimates of the total number of ESRD facilities, the total number of patients nationally, and wages for Medical Records Specialists or similar staff, as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting. In this proposed rule, we estimate that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. We are further updating these estimates in this proposed rule. There are 126 data elements proposed for 514,406 patients across 7,847 facilities, for a total of 64,815,156 elements (126 data elements x 514,406 patients). At 2.5 minutes per element, this would yield approximately 344 hours per facility. Therefore, the PY 2026 burden would be 2,700,632 hours (344 hours x 7,847 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2026 total burden cost is approximately \$121.1 million (2,700,632 hours x \$44.86).

There would also be an incremental burden change from PY 2026 to PY 2027 because we are proposing to add two new measures beginning with PY 2027. For PY 2027, there are 136 data elements proposed for 514,406 patients across 7,847 facilities. At 2.5 minutes per element, this would yield approximately 371 hours per facility. Therefore, the PY 2027 burden would be 2,914,967 hours (371 hours x 7,847 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2027 total burden cost would be approximately \$130.7 million (2,914,967 hours x \$44.86).

If you comment on these information collection requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule. Comments must be received on/by August 25, 2023.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This proposed rule proposes updates and policy changes to the CY 2024 ESRD wage index values, the proposed combined wage index and TPEAPA budget-neutrality adjustment factor, the outlier payment threshold amounts, and the TPNIES offset amount. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2024 for renal dialysis services furnished to ESRD beneficiaries.

This rule also has a number of proposed policy changes to improve payment stability and adequacy under the ESRD PPS. These include a proposed transitional add-on payment

adjustment for pediatric patients and a proposed add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA. We are also proposing updates to the administrative process for the LVPA, requiring ESRD facilities to report on claims billing units of any discarded amounts of certain drugs and biological products, and requiring ESRD facilities to report “time on machine” data on ESRD PPS claims for all in-center hemodialysis treatments. We believe that each of these changes would improve payment stability and adequacy under the ESRD PPS.

2. AKI

This proposed rule proposes updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section III.B of this proposed rule, we are also proposing to apply to all AKI dialysis payments the updates to the ESRD PPS base rate and wage index. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2024 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS by up to two percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This proposed rule proposes updates for the ESRD QIP, including removing the Ultrafiltration Rate reporting measure from the ESRD QIP measure set beginning with PY 2026, removing the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026, updating the COVID-19 Vaccination Coverage Among HCP beginning with PY 2026, converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure beginning with PY 2026, and adding the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026. This proposed rule also proposes to add the Screening for Social

Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027.

4. ETC Model

We believe it is necessary to propose certain changes to the ETC Model to acknowledge the availability of administrative review of targeted review requests. This proposed revision is necessary to provide transparency to ETC Participants regarding the avenue available to them should they wish to seek additional review of the results of a targeted review request determination.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 (Modernizing Regulatory Review) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity,

competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) of Executive Order 12866 (\$200 million or more in any 1 year). Based on our estimates of the combined impact of the ESRD PPS, ESRD QIP, and ETC provisions in this proposed rule, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) economic effect. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this proposed rule, and the Department have provided the following assessment of its impact. We solicit comments on the regulatory impact analysis provided.

C. Impact Analysis

1. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately \$130 million in Medicare payments to ESRD facilities in CY 2024, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, the budget-neutral transitional pediatric ESRD add-on payment adjustment, the beginning of the proposed post-TDAPA add-on payment adjustment, and continuation of the approved TDAPA from CY 2023 until March 31, 2024.

2. AKI

We estimate that the proposed updates to the AKI payment rate would result in an increase of approximately \$1 million in Medicare payments to ESRD facilities in CY 2024.

3. ESRD QIP

We estimate that the proposed updates to the ESRD QIP will result in \$20 million in estimated payment reductions across all facilities for PY 2026.

4. ETC Model

We estimate that the proposed changes to the ETC Model would not impact the Model's projected direct savings from payment adjustments alone. As described in the CY 2023 ESRD PPS final rule, we estimate that the Model would generate \$28 million in direct savings related to payment adjustments over 6.5 years (87 FR 67297 through 67299).

5. Summary of Impacts

We estimate that the combined impact of the proposals in this rule on payments for CY 2024 is \$131 million based on the estimates of the updates to the ESRD PPS and the AKI payment rates. We estimate an additional \$4 million in costs associated with the proposed policy to require ESRD facilities to report time on machine data. We estimate the impacts of the ESRD QIP for PY 2026 to be \$121.1 million in information collection burden and \$20 million in estimated payment reductions across all facilities. Additionally, we estimate the impacts of the ESRD QIP for PY 2027 to be \$130.7 million in information collection burden and \$17.3 million in estimated payment reductions across all facilities. Finally, we estimate that the proposed changes to the ETC model in this proposed rule would not impact the Model's projected direct savings from payment adjustments alone.

D. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this proposed rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this proposed rule.

1. Benefits

Under the CY 2024 ESRD PPS and AKI payment, ESRD facilities would continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective Medicare payments to ESRD facilities would enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished at ESRD facilities by 1.7 percent based on the proposed CY 2024 ESRD PPS market basket percentage increase less the proposed CY 2024 productivity adjustment would improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that the overall payment rate for the ESRD PPS would increase by 1.6 percent.

2. Costs

a. ESRD PPS and AKI

As discussed in section II.B.1.j of this proposed rule, we are proposing to require ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use would be used to apportion composite rate costs for use in the case-mix adjustment under the ESRD PPS. We estimate that there would be an increase in costs for ESRD facilities associated with this proposed reporting requirement; however, as we previously noted in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), we are aware that many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every dialysis treatment, minimizing the additional burden of reporting this metric on claims. For those ESRD facilities that use EHRs, we estimate that there would be only very minimal additional staff time required to report such time on machine data on ESRD PPS claims for renal dialysis services. For those ESRD facilities that do not use EHRs, we estimate that additional staff time would be required to take note of the

time at which hemodialysis began and the time at which hemodialysis ended, and subtract the start time from the end time to determine the total number of minutes of hemodialysis.

Conservatively, we estimate this would require no more than 1 minute per treatment.

To calculate the annual additional ESRD facility staff time that would be associated with reporting time on machine data on ESRD PPS claims for renal dialysis services, we multiply the estimated time per treatment by the number of dialysis treatments. Based on the most recent available CY 2022 ESRD PPS claims for this proposed rule, we estimate there were approximately 29.8 million treatments. However, as discussed in section II.B.1.j, we are proposing to limit this reporting requirement to in-center claims. We estimate that approximately 14.6 percent of claims are for home dialysis, and therefore we reduce our estimate of the total number of treatments by 14.6 percent. Additionally, we believe it is reasonable to assume that LDOs would utilize existing systems and processes to document treatment duration in the EHR and send that information to the claim. Based on the latest available data as shown in Table 23, approximately 77.9 percent of treatments were furnished by LDOs. Therefore, we estimate that the additional costs associated with this proposed time on machine reporting requirement would be associated with approximately 5.6 million in-center, non-LDO dialysis treatments per year.

Additionally, ESRD facilities already report time on machine data on a monthly basis in the EQRS for a single dialysis session. This means that for a patient who receives 156 dialysis treatments per year, the duration of twelve of those sessions would already be reported in the EQRS. We do not believe there would be any additional staff time required to report time on machine data on ESRD PPS claims for the treatments already reported in EQRS. Therefore, we estimate that the additional staff time would be needed for reporting time on machine for 144 out of 156 treatments per year for the typical patient. For our cost estimate, we multiplied our estimate of 5.6 million in-center dialysis treatments by a factor of $(144 / 156)$, which equals approximately 5.2 million treatments per year.

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates. We believe it is reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals reporting time on machine data. As discussed in the CY 2016 ESRD PPS final rule (80 FR 69069), this is consistent with our assumptions about the types of employees tasked with submitting measure data to CROWNWeb (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. The most recently available median hourly wage of a Medical Records and Health Information Technician is \$23.67 per hour.³⁰⁵ We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. We note that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Therefore, using these assumptions, we estimate an hourly labor cost of \$47.34 as the basis of the wage estimates for the estimate of cost associated with the proposed requirement to report time on machine data on ESRD PPS claims for renal dialysis services.

Based on the figures discussed in the preceding paragraphs, we estimate that total additional staff time each year for ESRD facilities associated with the proposed requirement to report time on machine data is equal to $5.2 \text{ million} \times 1 \text{ minute} = 5.2 \text{ million minutes} = 86,667 \text{ hours}$. We estimate the total annual cost associated with this proposed requirement is equal to $86,667 \text{ hours} \times \$47.34 = \$4,102,815.78$ per year.

We recognize that some non-LDO ESRD facilities may also choose to adopt an automated process, rather than a manual process. Therefore, the estimate of \$4,102,815.78,

³⁰⁵ <https://www.bls.gov/oes/current/oes292099.htm>.

calculated based on 5.2 million treatments, represents the upper limit of our burden estimate. For ESRD facilities that choose to utilize existing systems and processes to document treatment duration in the EHR and send that data to the claim, we estimate the burden associated with our proposed requirement to report time on machine data would be minimal.

b. ESRD QIP

For PY 2026 and PY 2027, we have updated the estimated costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of ESRD facilities, the total number of patients nationally, wages for Medical Records Specialists or similar staff, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the EQRS validation study (previously known as the CROWNWeb validation study) or the NHSN validation study. We have updated our methodology for calculating the annual burden associated with the information collection requirements for EQRS reporting based on our proposed measure updates for PY 2026 and PY 2027.

We also updated the payment reduction estimates based on our proposals in this proposed rule, using more recent data for the measures in the ESRD QIP measure set. We estimate that as a result of our proposed and previously finalized policies for PY 2026, there would be approximately \$121.1 million in information collection burden and an additional \$20 million in estimated payment reductions across all facilities, for a total estimated impact of \$141.1 million.

For PY 2027, we estimate that as a result of our proposed and previously finalized policies for PY 2027, there would be approximately \$130.7 million in information collection burden and \$17.3 million in estimated payment reductions across all facilities, for a total estimated impact of \$148 million.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rate would result in a total increase of approximately \$130 million in Medicare payments to ESRD facilities in CY 2024, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately \$1 million in Medicare payments to ESRD facilities in CY 2024 due to the updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary co-insurance payments. We estimate approximately \$100 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately \$30 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary co-insurance payments as a result of this proposed rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the proposed rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the

purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this proposed rule is \$115.22 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm).

Assuming an average reading speed, we estimate that it will take approximately 206 minutes (3.43 hours) for the staff to review half of this proposed rule, which has a total of approximately 103,000 words. For each entity that reviews the rule, the estimated cost is \$395.20 (3.43 hours x \$115.22). Therefore, we estimate that the total cost of reviewing this regulation is \$115,003.20 (\$395.20 x 291).

5. Impact Statement and Table

a. CY 2024 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2023 to estimated payments in CY 2024. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2023 and CY 2024 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we are able to calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we used CY 2022 data from the Medicare Part A and Part B Common Working Files as of 2/17/2023, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2022 claims to 2023 and 2024 using various updates. The updates to the ESRD PPS base rate are described in section II.B.1.d of this proposed rule. Table 23 shows the impact of the estimated CY 2024 ESRD PPS payments compared to estimated Medicare payments to ESRD facilities in CY 2023.

TABLE 23: Impacts of the Proposed Changes in Medicare Payments to ESRD Facilities for CY 2024

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	TPEAPA (D)	Changes to TDAPA and Post-TDAPA Payments ^{1,2} (E)	Wage Index Changes (F)	Total Percent Change ³ (G)
All Facilities	7,833	29.8	-0.1%	0.0%	0.0%	0.0%	1.6%
Type							
Freestanding	7,481	28.6	-0.1%	0.0%	0.0%	0.0%	1.6%
Hospital based	352	1.1	-0.2%	0.8%	0.0%	0.2%	2.6%
Ownership Type							
Large dialysis organization	6,068	23.2	-0.1%	0.0%	0.0%	0.0%	1.6%
Regional chain	901	3.6	-0.1%	0.0%	-0.1%	-0.1%	1.4%
Independent	451	1.7	-0.1%	0.0%	0.0%	0.6%	2.2%
Hospital based	352	1.1	-0.2%	0.8%	0.0%	0.2%	2.6%
Unknown	61	0.0	0.0%	0.0%	0.0%	0.2%	1.8%
Geographic Location							
Rural	1,264	4.2	-0.1%	0.0%	0.0%	-0.5%	1.1%
Urban	6,569	25.6	-0.1%	0.0%	0.0%	0.1%	1.7%
Census Region							
East North Central	1,223	4.0	-0.1%	0.0%	0.0%	-0.4%	1.2%
East South Central	616	2.0	-0.1%	0.0%	0.0%	-0.4%	1.2%
Middle Atlantic	893	3.7	-0.1%	0.0%	0.0%	0.8%	2.4%
Mountain	438	1.6	-0.1%	0.0%	0.0%	-0.5%	1.1%
New England	200	1.0	-0.1%	0.0%	0.0%	-0.5%	1.1%
Pacific ⁴	977	5.1	-0.1%	0.0%	0.0%	0.0%	1.6%
Puerto Rico and Virgin Islands	52	0.1	0.0%	0.0%	0.0%	0.0%	1.7%
South Atlantic	1,820	6.5	-0.1%	0.0%	0.0%	0.2%	1.8%
West North Central	495	1.7	-0.1%	0.0%	0.0%	-0.4%	1.2%
West South Central	1,119	4.0	-0.1%	0.1%	0.0%	-0.1%	1.6%
Facility Size							
Less than 4,000 treatments	1,267	1.5	-0.1%	0.3%	0.0%	-0.1%	1.9%

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	TPEAPA (D)	Changes to TDAPA and Post-TDAPA Payments ^{1,2} (E)	Wage Index Changes (F)	Total Percent Change ³ (G)
4,000 to 9,999 treatments	3,294	9.2	-0.1%	0.0%	0.0%	-0.1%	1.5%
10,000 or more treatments	3,272	19.0	-0.1%	0.0%	0.0%	0.0%	1.6%
Unknown	0	0.0	0.0%	0.0%	0.0%	0.0%	0.0%
Percentage of Pediatric Patients							
Less than 2%	7,732	29.6	-0.1%	0.0%	0.0%	0.0%	1.6%
Between 2% and 19%	37	0.2	-0.1%	1.5%	0.0%	-0.7%	2.5%
Between 20% and 49%	9	0.0	0.0%	8.6%	0.0%	-1.1%	9.3%
More than 50%	55	0.0	0.1%	25.2%	0.0%	0.0%	27.6%

¹This column includes the impact of the end of TDAPA payment for KORSUVA™ and the start of the proposed post-TDAPA payment adjustment beginning in April, 2024. This proposed change is not budget neutral, but we estimate the overall change in total payments would be a decrease of less than 0.1 percent.

²CY 2023 TDAPA for KORSUVA™ will continue through March 31, 2024, under the ESRD PPS. We estimate approximately \$1.7 million in TDAPA spending, of which, approximately \$345,000 would be attributed to beneficiary coinsurance amounts.

³ This column includes the impact of the proposed updates in columns (C) through (F) in Table 23, and of the proposed ESRDB market basket percentage increase for CY 2024 of 2.0 percent, reduced by 0.3 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

⁴ Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.1.c of this proposed rule is shown in column C. For CY 2024, the impact on all ESRD facilities as a result of the proposed changes to the outlier payment policy would be a 0.1 percent decrease in estimated Medicare payments.

Column D shows the effect of the proposed TPEAPA as described in section II.B.1.g of this proposed rule. This adjustment would be implemented in a budget neutral manner, so the total impact of this change would be 0.0 percent. However, there would be distributional impacts of this proposed change, primarily a 25.2 percent increase to payments to Pediatric

ESRD facilities (with more than 50 percent of patients under age 18). This proposed policy change also corresponds to a 0.8 percent increase to hospital-based ESRD facilities. Because the budget neutrality factor for this proposed policy is so small, the impact analysis found no significant decrease to any ESRD facility as the total decrease in payments for ESRD facilities that predominantly serve adults would still be less than 0.05 percent.

Column E shows the effect of year-over-year payment changes related to the proposed post-TDAPA add-on payment adjustment as described in section II.B.1.i of this proposed rule and current TDAPA payments. The post-TDAPA add-on payment adjustment would not be budget neutral; however, we estimate the difference between total payments in CY 2023 during which time payment is made using the TDAPA under the ESRD PPS, and estimated total payments in CY 2024 under the proposed post-TDAPA add-on payment adjustment would be less than 0.1 percent. Therefore, the total impact of this change as compared to current TDAPA payments is 0.0 percent.

Column F reflects the effect of the proposed update to the ESRD PPS wage index as described in section II.B.1.c of this proposed rule. This update would be budget neutral, so the total impact of this policy change is 0.0 percent. However, there would be distributional impacts of this change. The largest increase would be to mid-Atlantic ESRD facilities that would receive 0.8 percent higher payments as a result of the proposed updated ESRD PPS wage index. The largest decrease would be to ESRD facilities with more than 20 percent and less than 50 percent pediatric patients, who would receive 1.1 percent lower payments as a result of the proposed updated ESRD PPS wage index.

Column G reflects the overall impact, that is, the effects of the proposed outlier policy changes, the TPEAPA, the post-TDAPA payment adjustment, the updated wage index, and the payment rate update as proposed in section II.B.1.d of this proposed rule. The proposed ESRD PPS payment rate update for CY 2024 is 1.7 percent, which reflects the proposed ESRDB market basket percentage increase for CY 2024 of 2.0 percent and the proposed productivity adjustment

of 0.3 percent. We expect that overall ESRD facilities would experience a 1.6 percent increase in estimated Medicare payments in CY 2024. The categories of types of ESRD facilities in the impact table show impacts ranging from a 1.1 percent increase to a 27.6 percent increase in their CY 2024 estimated Medicare payments.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2024, we estimate that the ESRD PPS would have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2024 would be approximately \$6.4 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 4.2 percent in CY 2024.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.6 percent overall increase in the CY 2024 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2024, which translates to approximately \$30 million.

(5) Alternatives Considered

(i) Transitional Pediatric ESRD Add-On Payment Adjustment

As discussed in section II.B.1.g.(4) of this proposed rule, we are proposing to implement a transitional add-on payment adjustment of 30 percent for Pediatric ESRD Patients, which we would call the TPEAPA. We also considered, but did not propose, an alternative payment

structure which would phase in the adjustment over 3 years starting at 10 percent for the first year and 20 percent for the second year.

(ii) Proposed Add-on Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products after the TDAPA Period Ends

As discussed in section II.B.1.i.(3) of this proposed rule, we are proposing an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We also considered, but did not propose, an alternative methodology for calculating this payment adjustment which would incorporate a reconciliation of all the formerly separately billable drugs against the calculated post-TDAPA payment adjustment. Additionally, we considered but did not propose alternative approaches to applying and calculating this add-on payment adjustment for specific patient populations.

(iii) Proposal to Require Reporting Time on Machine Data on ESRD PPS Claims for Renal Dialysis Services

As discussed in section II.B.1.j.(5) of this proposed rule, we are proposing to require ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use would be used to apportion composite rate costs for use in the case-mix adjustment. We also considered, but did not propose, to use dialysis duration data from EQRS to apportion composite rate costs for this purpose. We discuss why we did not propose this alternative in further detail in section II.B.1.j.(5) of this proposed rule.

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2024

(1) KORSUVA™ (difelikefalin)

One renal dialysis drug for which the TDAPA was paid in CY 2022 and CY 2023 would continue to be eligible for the TDAPA in CY 2024. CMS Transmittal 11295,³⁰⁶ implemented the 2-year TDAPA period specified in § 413.234(c)(1) for KORSUVA™ (difelikefalin). The TDAPA payment period began on April 1, 2022 and will continue through March 31, 2024. As set forth in § 413.234(c), TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based the CY 2024 impacts on the most current 72x claims data from May 2022, when utilization first appeared on the claims, through February 2023. During that timeframe, the average monthly TDAPA payment amount for KORSUVA™ was \$575,000. In applying that average to the 3 remaining months of the TDAPA payment period in CY 2024, we estimate \$1,725,000 in spending ($\$575,000 * 3 = \$1,725,000$) of which, approximately \$345,000 ($\$1,725,000 * 0.20 = \$345,000$) would be attributed to beneficiary coinsurance amounts.

c. Payment for Renal Dialysis Services Furnished to Individuals with AKI

(1) Effects on ESRD Facilities

To understand the impact of the proposed changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2023 to estimated Medicare payments in CY 2024. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2023 and CY 2024 contain similar inputs. Therefore, we simulated Medicare

³⁰⁶ CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022 and is available at: <https://www.cms.gov/files/document/r11295CP.pdf>.

payments only for those ESRD facilities for which we are able to calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we used CY 2022 data from the Medicare Part A and Part B Common Working Files as of 2/17/2023, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2022 claims to 2023 and 2024 using various updates. The proposed updates to the AKI payment amount are described in section III.B of this proposed rule. Table 24 shows the impact of the estimated CY 2024 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2023.

TABLE 24: Impacts of the Proposed Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2024

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change ¹ (D)
All Facilities	5,048	268.1	-0.1%	1.6%
Type				
Freestanding	4,934	262.9	-0.1%	1.6%
Hospital based	114	5.2	0.2%	1.8%
Ownership Type				
Large dialysis organization	4,159	220.3	-0.1%	1.5%
Regional chain	576	28.6	-0.1%	1.5%
Independent	174	13.3	0.6%	2.3%
Hospital based ²	114	5.2	0.2%	1.8%
Unknown	25	0.8	0.2%	1.8%
Geographic Location				
Rural	854	41.3	-0.5%	1.2%
Urban	4,194	226.8	0.0%	1.6%
Census Region				
East North Central	847	43.8	-0.4%	1.2%
East South Central	379	18.0	-0.3%	1.3%
Middle Atlantic	527	31.4	0.7%	2.4%
Mountain	298	19.3	-0.7%	0.9%
New England	145	6.5	-0.3%	1.3%
Pacific ³	617	41.3	-0.2%	1.5%
Puerto Rico and Virgin Islands	5	0.1	0.0%	1.7%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change ¹ (D)
South Atlantic	1,215	63.9	0.1%	1.7%
West North Central	314	12.6	-0.3%	1.3%
West South Central	701	31.1	0.0%	1.7%
Facility Size				
Less than 4,000 treatments	565	22.2	0.0%	1.7%
4,000 to 9,999 treatments	2,160	102.9	-0.1%	1.5%
10,000 or more treatments	2,323	143.0	-0.1%	1.6%
Unknown	0	0.0	0.0%	0.0%
Percentage of Pediatric Patients				
Less than 2%	5,036	267.6	-0.1%	1.6%
Between 2% and 19%	10	0.5	-2.0%	-0.4%
Between 20% and 49%	1	0.1	-1.6%	0.0%
More than 50%	1	0.0	-0.5%	1.2%

¹ This column includes the impact of the proposed updates in columns (C) as well as the impact of the proposed TPEAPA budget-neutrality adjustment factor in Table 24, and of the proposed ESRDB market basket percentage increase for CY 2024 (2.0 percent), reduced by 0.3 percentage point for the proposed productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

² Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

³ Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the CY 2024 wage indices.

Column D shows the overall impact, that is, the effects of proposed combined wage index and TPEAPA budget-neutrality adjustment factor, wage index updates, and the payment rate update of 1.7 percent, which reflects the proposed ESRDB market basket percentage increase for CY 2024 of 2.0 percent and the proposed productivity adjustment of 0.3 percentage point. We expect that overall ESRD facilities would experience a 1.6 percent increase in estimated Medicare payments in CY 2024. The categories of types of ESRD facilities in the impact table

show impacts ranging from an increase of -0.4 percent to 2.4 percent in their CY 2024 estimated Medicare payments.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately \$70 million would be paid to ESRD facilities in CY 2024 as a result of patients with AKI receiving renal dialysis services in an ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI

specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients, and as such, including those policies and adjustments is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring would assist us in developing knowledgeable, data-driven proposals.

d. ESRD QIP

(1) Effects of the PY 2026 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's TPS is described in our regulations at 42 CFR 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2026 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2026, as codified in our regulations at 42 CFR 413.177.

For the PY 2026 ESRD QIP, we estimate that, of the 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 31.56 percent or 2,477 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2026. Among an estimated 2,477 facilities that would receive a payment reduction, approximately 64 percent or 1,585 facilities would receive the smallest payment reduction of 0.5 percent. We are presenting an estimate for the PY 2026 ESRD QIP to update the estimated impact that was provided in the CY 2023 ESRD PPS final rule (87 FR 67293 through 67296). Based on our proposed policies, the total estimated payment reductions for all the 2,477 facilities expected to receive a payment reduction in PY 2026 would be approximately \$20,040,827. Facilities that do not receive a TPS do not receive a payment reduction.

Table 25 shows the overall estimated distribution of payment reductions resulting from the PY 2026 ESRD QIP.

TABLE 25: Estimated Distribution of PY 2026 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5175	67.63%
0.5%	1585	20.71%
1.0%	673	8.80%
1.5%	176	2.30%
2.0%	43	0.56%

*195 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2026, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 19) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 26.

TABLE 26: Data Used to Estimate PY 2026 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021
Clinical Depression*	N/A	Jan 2021-Dec 2021

*Note: PPPW score and Clinical Depression score are based on achievement score only.

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at

least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the proposed policies outlined in section IV.C of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2021. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2026 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 27 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2026. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2026 ESRD QIP, the actual impact of the PY 2026 ESRD QIP may vary significantly from the values provided here.

TABLE 27: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,847	35.0	7,652	2,477	-0.23%
Facility Type:					
Freestanding	7,471	33.7	7,315	2,336	-0.23%
Hospital-based	376	1.4	337	141	-0.33%
Ownership Type:					
Large Dialysis	5,964	27.1	5,881	1,679	-0.19%
Regional Chain	904	4.3	893	364	-0.31%
Independent	466	2.1	451	252	-0.50%
Hospital-based (non-chain)	376	1.4	337	141	-0.33%
Unknown	137	0.1	90	41	-0.63%
Facility Size:					
Large Entities	6,868	31.4	6,774	2,043	-0.20%
Small Entities ¹	842	3.5	788	393	-0.43%
Unknown	137	0.1	90	41	-0.63%
Rural Status:					
1) Yes	1,281	5.0	1,244	326	-0.17%
2) No	6,566	30.0	6,408	2,151	-0.24%
Census Region:					
Northeast	1,087	5.5	1,059	372	-0.26%
Midwest	1,736	6.6	1,681	552	-0.24%
South	3,570	15.2	3,482	1,205	-0.25%
West	1,393	7.4	1,370	307	-0.15%
US Territories ²	61	0.3	60	41	-0.45%
Census Division:					
Unknown	9	0.1	9	5	-0.27%
East North Central	1,222	4.7	1,198	438	-0.27%
East South Central	618	2.4	602	188	-0.21%
Middle Atlantic	886	4.3	860	317	-0.27%
Mountain	436	1.9	428	100	-0.15%
New England	201	1.2	199	55	-0.20%
Pacific	957	5.5	942	207	-0.15%
South Atlantic	1,827	8.0	1,778	652	-0.26%
West North Central	514	1.9	483	114	-0.16%
West South Central	1,125	4.8	1,102	365	-0.25%
US Territories ²	52	0.1	51	36	-0.48%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,229	1.9	1,138	244	-0.18%
4,000-9,999 treatments	3,095	10.1	3,061	865	-0.20%
Over 10,000 treatments	3,358	22.9	3,355	1,321	-0.27%
Unknown	165	0.2	98	47	-0.67%

¹Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.

²Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(3) Effects of the PY 2027 ESRD QIP on ESRD Facilities

For the PY 2027 ESRD QIP, we estimate that, of the 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 29.29 percent or 2,299 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2027. Among an estimated 2,299 facilities that would receive a payment reduction, approximately 68.3 percent or 1,571 facilities would receive the smallest payment reduction of 0.5 percent. The total payment reductions for all the 2,299 facilities expected to receive a payment reduction is

approximately \$17,388,145. Facilities that do not receive a TPS do not receive a payment reduction.

Table 28 shows the overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 28: Estimated Distribution of PY 2027 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5432	70.26%
0.5%	1571	20.32%
1.0%	606	7.84%
1.5%	118	1.53%
2.0%	4	0.05%

*Note: 116 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2027, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 26) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 29.

TABLE 29: Data Used to Estimate PY 2027 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021
Clinical Depression*	N/A	Jan 2021-Dec 2021

*Note: PPPW score and Clinical Depression score are based on achievement score only

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that

facility's TPS. For the SHR and SRR measures, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the proposed and previously finalized policies outlined in section IV.D of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2021. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2027 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 30 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2027. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

TABLE 30: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,847	35.0	7,731	2,299	-0.20%
Facility Type:					
Freestanding	7,471	33.7	7,384	2,168	-0.20%
Hospital-based	376	1.4	347	131	-0.28%
Ownership Type:					
Large Dialysis	5,964	27.1	5,900	1,536	-0.16%
Regional Chain	904	4.3	893	354	-0.28%
Independent	466	2.1	460	237	-0.42%
Hospital-based (non-chain)	376	1.4	347	131	-0.28%
Unknown	137	0.1	131	41	-0.32%
Facility Size:					
Large Entities	6,868	31.4	6,793	1,890	-0.18%
Small Entities ¹	842	3.5	807	368	-0.36%
Unknown	137	0.1	131	41	-0.32%
Rural Status:					
1) Yes	1,281	5.0	1,255	313	-0.15%
2) No	6,566	30.0	6,476	1,986	-0.21%
Census Region:					
Northeast	1,087	5.5	1,076	329	-0.21%
Midwest	1,736	6.6	1,703	515	-0.20%
South	3,570	15.2	3,514	1,138	-0.22%
West	1,393	7.4	1,378	277	-0.13%
US Territories ²	61	0.3	60	40	-0.43%
Census Division:					
Unknown	9	0.1	9	5	-0.27%
East North Central	1,222	4.7	1,206	409	-0.23%
East South Central	618	2.4	607	179	-0.19%
Middle Atlantic	886	4.3	876	284	-0.22%
Mountain	436	1.9	431	97	-0.14%
New England	201	1.2	200	45	-0.16%
Pacific	957	5.5	947	180	-0.12%
South Atlantic	1,827	8.0	1,799	617	-0.23%
West North Central	514	1.9	497	106	-0.13%
West South Central	1,125	4.8	1,108	342	-0.22%
US Territories ²	52	0.1	51	35	-0.46%
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,229	1.9	1,173	233	-0.15%
4,000-9,999 treatments	3,095	10.1	3,061	839	-0.18%
Over 10,000 treatments	3,358	22.9	3,355	1,180	-0.23%
Unknown	165	0.2	142	47	-0.34%

¹Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.

²Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(4) Effects on Other Providers

The ESRD QIP is applicable to ESRD facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions

Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(5) Effects on the Medicare Program

For PY 2027, we estimate that the ESRD QIP would contribute approximately \$17,388,145.07 in Medicare savings. For comparison, Table 31 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2027.

TABLE 31: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2027

Payment Year	Estimated Payment Reductions
PY 2027	\$17,388,145
PY 2026	\$20,040,827
PY 2025	\$32,457,693 (87 FR 67297)
PY 2024	\$17,104,031 (86 FR 62011)
PY 2023	\$5,548,653 (87 FR 67297)
PY 2022	\$0 ³⁰⁷ (86 FR 62011)
PY 2021	\$32,196,724 (83 FR 57062)
PY 2020	\$31,581,441 (81 FR 77960)
PY 2019	\$15,470,309 (80 FR 69074)
PY 2018	\$11,576,214 (79 FR 66257)

(6) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new

³⁰⁷ In the CY 2022 ESRD PPS final rule, we adopted a special scoring methodology and payment policy for PY 2022 due to significant impacts related to the COVID-19 public health emergency (86 FR 61918 through 61919). Under this policy, we did not apply any payment reductions to ESRD facilities for PY 2022.

measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

(7) Alternatives Considered

In section IV.C.5 of this proposed rule, we are proposing to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure, beginning with PY 2026. We considered not proposing to remove these measures. However, we concluded that proposing to remove these two measures was appropriate under our previously finalized measure removal factors. This approach would help to ensure that a facility's performance is assessed based on measures that continue to be meaningful parts of the ESRD QIP measure set.

e. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), and the CY 2023 ESRD PPS final rule (87 FR 67136) for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021, to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. We are proposing to revise our regulations at § 512.390 to acknowledge the ability of the CMS Administrator to review the results of ETC Participants' targeted review requests. For the results of the detailed economic analysis of the ETC Model and a description of the methodology used to perform the analysis, please see the Specialty Care Models final rule (85 FR 61114).

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs

2018 and 2019 without the changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years of complete data available before the start of the ETC Model. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

Table 32 summarizes the estimated impact of the ETC Model when the achievement benchmarks for each year are set using the average of the home dialysis rates for year $t-1$ and year $t-2$ for the HRRs randomly selected for participation in the ETC Model. We estimate that the Medicare program would save a net total of \$43 million from the PPA and HDPA between January 1, 2021, and June 30, 2027 less \$15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be \$28 million in savings. This is consistent with the net impact to Medicare spending estimated for the CY 2022 ESRD PPS final rule, in which the net impact to Medicare spending was also estimated to be \$28 million in savings (86 FR 62014 through 62016). Our proposal to make administrative review available to ETC Participants who wish to seek additional review of a targeted review determination is not expected to change this estimate.

(3) Medicare Estimate – Primary Specification, Assume Rolling Benchmark

TABLE 32: Estimates of Medicare Program Savings (Rounded \$M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	2022	2023	2024	2025	2026	2027	6.5 Year Total*
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDP	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDP	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDP	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDP	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than \$1M each year, but are rounded up to \$1M to show what years they apply to. Similarly, the HD Training Costs are less than \$1M for years 2021-2024, but are rounded up to \$1M to indicate that costs were applied those years.

In Table 32, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for this table were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. For a detailed description of the key assumptions underlying the impact estimate, see the

Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The changes in this proposed rule would not impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes in this proposed rule will not impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) and the CY 2023 ESRD PPS final rule (87 FR 67136).

(6) Effects on Medicare Beneficiaries

Our proposal to provide the option for ETC Participants to seek administrative review of targeted review determinations will not impact the findings reported for the effects of ETC Model on Medicare beneficiaries in lieu of the ETC Model's likelihood of incentivizing ESRD facilities and Managing Clinicians to improve access to home dialysis and transplantation for Medicare beneficiaries. Further details on the impact of the ETC Model on ESRD Beneficiaries may be found in the Specialty Care Models final rule (85 FR 61357), the CY 2022 ESRD PPS final rule (86 FR 61874), or the CY 2023 ESRD PPS final rule (87 FR 67136).

(7) Alternatives Considered

In this proposed rule, we are proposing to revise our regulations at 42 CFR 512.390 to acknowledge the availability of administrative review of targeted review requests. We considered retaining our current process, in which targeted review determinations are final with no further review or appeal; however, we believe that providing for administrative review of targeted review determinations is important to provide ETC Participants with transparency regarding the avenue that is available should they wish to seek review of their targeted review

determination, to vest accountability for the decisions of CMS in a principal officer, and to bring the ETC Model into alignment with CMS programs.

E. Accounting Statement

As required by OMB Circular A-4 (available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement in Table 33 showing the classification of the impact associated with the provisions of this proposed rule.

TABLE 33: Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI (CY 2024)	
Category	Transfers
Annualized Monetized Transfers	\$100 million
From Whom to Whom	Federal Government to ESRD providers
Category	Transfers
Increased Beneficiary Co-insurance Payments	\$30 million
From Whom to Whom	Beneficiaries to ESRD providers
Category	Costs
Increased Reporting Burden for Time on Machine	\$4 million
For Whom	ESRD Facilities
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-\$20.0 million
From Whom to Whom	Federal Government to ESRD providers.
ESRD QIP for PY 2027	
Category	Transfers
Annualized Monetized Transfers	-\$17.3 million
From Whom to Whom	Federal Government to ESRD providers
ETC Model for July 1, 2022 through June 30, 2027	
Category	Transfers
Annualized Monetized Transfers	\$0.03 million
From Whom to Whom	Federal Government to ESRD facilities and Managing Clinicians

F. Regulatory Flexibility Act Analysis (RFA)

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore,

they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards, an ESRD facility is classified as a small business if it has total revenues of less than \$41.5 million in any 1 year. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than \$8.1 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 451 facilities that are independent and 352 facilities that are hospital-based, as shown in the ownership category in Table 23, to be small businesses. These facilities represent approximately 10 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 806 facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 364 nonprofit ESRD facilities that are also considered small businesses, there are 1,245 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

For the ESRD PPS updates in this proposed rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 2.6 percent increase in Medicare payments for CY 2024. An independent facility (as defined by ownership type) is likewise estimated to receive a 2.2 percent increase in Medicare payments for CY 2024.

As shown in Table 23, we estimate that the overall revenue impact of this proposed rule on all ESRD facilities is a positive increase to Medicare payments by approximately 1.6 percent.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for \$70 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 2,477 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2026 ESRD QIP, 393 are ESRD small entity facilities. We present these findings in Table 25 (“Estimated Distribution of PY 2026 ESRD QIP Payment Reductions”) and Table 27 (“Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026”).

Regarding the ETC Model, in the Specialty Care Models final rule, we described our assumption, for the purposes of the regulatory impact analysis, that the great majority of Managing Clinicians are small entities by nature of meeting the SBA definition of a small business, but that the greater majority of ESRD facilities are not, as they are owned, either partially or entirely, by organizations that do not meet the SBA definition of a small entity. We described the low volume threshold exclusions and aggregation policies used in the ETC Model and our assessment that, in conjunction with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaries; the ETC Model will not have a significant impact on spending for a substantial number of small entities. For the purposes of this proposed rule, we have determined that our proposal to clarify the ability of the CMS Administrator to review targeted review determinations will not change the assessment that the ETC Model will not have a significant impact on spending for a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA.

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 121 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 121 rural hospital-based ESRD facilities would experience an estimated 2.2 percent increase in payments. Therefore, the Secretary has certified that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Our proposal to clarify the ability of the CMS Administrator to review ETC Model targeted review determinations is not expected to change the Secretary's assessment.

G. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately \$177 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than \$177 million in any 1 year. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has

federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of State, local, or Tribal governments.

IX. Files Available to the Public

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet and will be posted on the CMS website under the regulation number, CMS-1782-P, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>. In addition to the Addenda, limited data set files (LDS) are available for purchase at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile>. Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: ESRDPayment@cms.hhs.gov.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 15, 2023.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413 - PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

2. Section 413.178 is amended by revising paragraphs (a)(8) and (c) to read as follows:

§ 413.178 ESRD quality incentive program.

(a) * * *

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if it performed at the 50th percentile of national ESRD facility performance on all clinical measures during the baseline period, and it performed at the median of national ESRD facility performance on all reporting measures using data from the most recently available year before the performance period.

* * * *

(c) *ESRD QIP measure selection, retention, and removal*—(1) *ESRD QIP measure selection.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include:

(i) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management;

(ii) Measures on dialysis adequacy;

(iii) To the extent feasible, a measure (or measures) of patient satisfaction;

(iv) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula);

(v) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based; and

(vi) Other measures that CMS specifies.

(2) *Use of endorsed measures*—(i) *General rule.* Measures specified by CMS under paragraph (c)(1) of this section will be endorsed by the entity with a contract under section 1890(a) of the Social Security Act, unless the exception in paragraph (c)(2)(ii) of this section applies.

(ii) *Exception.* CMS may specify a measure under paragraph (c)(1) of this section that does not meet the requirement in paragraph (c)(2)(i) of this section if:

(A) CMS has determined that a specified area or medical topic is appropriate for inclusion in the ESRD QIP;

(B) CMS has not identified a feasible and practical measure with respect to that specified area or medical topic that has been endorsed by the entity with a contract under section 1890(a) of the Social Security Act; and

(C) CMS has given due consideration to measures that have been endorsed or adopted by a consensus organization.

(3) *Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the ESRD QIP. CMS announces technical measure specification updates through the QualityNet website (<https://qualitynet.cms.gov>) and listserv announcements.

(4) *Measure retention.* All measures specified for the ESRD QIP measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(5) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a measure based on one or more of the following factors:

(A) *Factor 1.* Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made.

(B) *Factor 2.* Performance or improvement on a measure does not result in better or the intended patient outcomes.

(C) *Factor 3.* A measure no longer aligns with current clinical guidelines or practice.

(D) *Factor 4.* A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.

(E) *Factor 5.* A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative or unintended consequences.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception.* CMS may retain a measure that meets one or more of the measure removal factors described in paragraph (c)(5)(i) of this section for reasons including, but not limited to, that the measure addresses a gap in quality that is so significant that removing the measure would lower the quality of care furnished by facilities, or that the measure is statutorily required.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for facilities to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the ESRD QIP measure set. CMS will, upon removal of the measure --

(A) Provide notice to facilities and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if facilities continued to submit data on the measure; and

(B) Provide notice of the removal in the **Federal Register**.

* * * * *

3. Section 413.198 is amended by revising paragraphs (a) and (b)(3)(iii) and adding paragraphs (b)(5) and (6) to read as follows:

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and scope.* This section implements sections 1881(b)(2)(B)(i) and 1881(b)(14) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

(b) * * *

(3) * * *

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

* * * * *

(5) Each ESRD facility must submit data and information of the types and in the formats established by CMS for the purpose of estimating patient-level and facility-level variation in resource use involved in furnishing renal dialysis services. The data and information must include, but is not limited to:

(i) Beginning January 1, 2025, information reported on ESRD prospective payment system (PPS) claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility;

(ii) Information reported on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data); and

(iii) Information reported on ESRD PPS claims about any renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS for which there is no discarded amount, using the JZ modifier (or any successor modifier that includes the same data).

(6) Each ESRD facility must document in the beneficiary's medical record any discarded amounts of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS.

4. Section 413.230 is amended by revising paragraphs (d) and (e) and adding paragraph (f) to read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(d) Any transitional drug add-on payment adjustment under § 413.234(c);

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d); and

(f) Any add-on payment adjustment for new renal dialysis drugs or biological products in existing ESRD PPS functional categories after the payment period for the transitional drug add-on payment adjustment has ended, as described in § 413.234(c)(3) and (g).

5. Section 413.232 is amended by revising paragraphs (b)(1) and (2) and (g) introductory text and adding paragraphs (g)(5) and (6) to read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) * * *

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5) of this section) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year, except as specified in paragraph (g)(6) of this section.

* * * * *

(g) To receive the low-volume adjustment, an ESRD facility must include in its attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraphs (g)(4) and (5) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

* * * * *

(5) For payment year 2024 and subsequent payment years, an ESRD facility may attest in the attestation specified in paragraph (e) of this section that it would have met the requirements of paragraph (b)(1) of this section, except that for one or more of the most recent 3 cost reporting years the facility furnished 4,000 or more treatments because of temporary patient-shifting as a result of the closure or operational disruption of another ESRD facility due to a disaster or other emergency. For the purposes of the exception in this paragraph (g)(5), temporary patient-shifting is defined as providing renal dialysis services to one or more displaced patient(s) at any time through the end of the calendar year following the 12-month period beginning when an

ESRD facility first begins providing renal dialysis services to one or more displaced patients.

For any facility that so attests--

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(ii) The facility must request an exception under this paragraph (g)(5) from CMS, in the form and manner specified by CMS, no later than the attestation deadline specified in paragraph (e) of this section for each cost reporting year that the facility furnishes treatments equal to or in excess of 4,000 due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(iii) Within 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency, or deny the request, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility is paid the low-volume adjustment on claims for Medicare beneficiaries for up to the first 4,000 dialysis treatments, on the basis of the exception in this paragraph (g)(5), during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. For any future payment year, the ESRD facility would not be prevented from receiving the low-volume adjustment if the ESRD facility meets or exceeds the 4,000 treatment threshold in a cost reporting year due to temporary patient-shifting as a result of the disaster or other emergency that resulted in another ESRD facility's closure or operational disruption, so long as all other requirements for the low-volume adjustment are met; and

(v) The facility must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that closed or experienced operational disruptions due to a disaster or other emergency and previously treated those patients, and must provide such supporting documentation to CMS and the MAC upon request.

(6) In the case of an ESRD facility that closes due to a disaster or other emergency and later reopens, the ESRD facility may attest in the attestation specified in paragraph (e) of this section that CMS has granted an exception to the requirements specified in paragraph (b)(2) of this section because it closed due to a disaster or other emergency. For any facility that so attests--

(i) The ESRD facility would need to request such an exception from CMS, in the form and manner specified by CMS, within 60 days of the facility's closure, and the ESRD facility must inform the MAC of this request in writing;

(ii) With 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and will inform both the facility and the MAC of its decision; and

(iii) If CMS approves the request, the exception under this paragraph (g)(6) will be applicable for a period consisting of the remainder of the cost reporting year (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) in which the closure occurred and the following full 2 cost reporting years. After this period the ESRD facility would follow the general attestation process for the low-volume adjustment specified in paragraphs (e) and (g) of this section.

(iv) The ESRD facility that attests under this paragraph (g)(6) to have closed due to a disaster or other emergency would need to notify CMS and the MAC, in the form and manner specified by CMS, within 30 days reopening and providing renal dialysis services. Within 30 days of CMS's receipt of the facility's notification, CMS will confirm receipt to the facility and

the MAC of the facility's notification and the ESRD facility will be able to receive the low-volume adjustment as of the date of reopening, so long as all other requirements for the low-volume adjustment are met.

(v) The ESRD facility must maintain documentation regarding its closure, and must provide such supporting documentation to CMS and/or the MAC upon request.

* * * * *

6. Section 413.234 is amended by—

- a. Adding paragraph (b)(1)(iii);
- b. Revising paragraph (c)(1)(i); and
- c. Adding paragraphs (c)(1)(ii), (c)(3), and (g).

The additions and revision read as follows:

§ 413.234 Drug designation process.

* * * * *

(b) * * *

(1) * * *

(iii) The new renal dialysis drug or biological product is paid for using the add-on payment adjustment described in paragraphs (c)(3) and (g) of this section, referred to as the post-transitional drug add-on payment adjustment (TDAPA) add-on payment adjustment.

* * * * *

(c) * * *

(1) * * *

(i) Following payment of the transitional drug add-on payment adjustment, the new renal dialysis drug or biological product is paid the post-TDAPA add-on payment adjustment as set forth in paragraphs (c)(3) and (g) of this section.

(ii) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.

* * * * *

(3) For any new renal dialysis drug or biological product that is eligible for payment using the transitional drug add-on payment adjustment described in paragraphs (b)(1)(iii) and (c)(1) of this section, CMS applies a post-TDAPA add-on payment adjustment to all ESRD PPS claims that is calculated using the methodology set forth in paragraph (g) of this section. CMS will apply the post-TDAPA add-on payment adjustment beginning 8 calendar quarters after the first calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product, and ending 12 calendar quarters after the end of the last calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product. If CMS stops receiving the latest full calendar quarter of ASP data for the applicable renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) of this section or during the 3-year period following such applicable time period, CMS will not pay any post-TDAPA add-on payment adjustment for such product in any future year.

* * * * *

(g) *Post-TDAPA add-on payment adjustment methodology.* CMS uses the following methodology to calculate the post-TDAPA add-on payment adjustment described in paragraph (c)(3) of this section:

(1) CMS bases the calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. If the most recent full calendar quarter of ASP data reflects zero or negative sales, then the calculation is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

(2) CMS calculates the post-TDAPA add-on payment adjustment annually as the expenditure for the new renal dialysis drug or biological product divided by the total number of ESRD PPS treatments during the same period.

(3) CMS applies a reduction factor to the post-TDAPA add-on payment adjustment for case mix standardization to reflect estimated increases resulting from the application of the patient-level adjustments as described in paragraph (g)(5) of this section. This reduction factor is calculated based on the patient-level adjustments (as described in § 413.235) applicable to the most recent 12-month period of utilization of ESRD PPS claims.

(4) The amount of the post-TDAPA add-on payment adjustment is equal to 65 percent of the amount calculated in paragraph (g)(2) of this section, multiplied by the reduction factor specified in paragraph (g)(3) of this section, and multiplied by the market basket increase factor under § 413.220(a)(5).

(5) The post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjusted by any applicable patient-level case-mix adjustments under § 413.235.

7. Section 413.235 is amended by revising paragraph (b) to read as follows:

§ 413.235 Patient-level adjustments.

* * * * *

(b) CMS adjusts the per treatment base rate for Pediatric ESRD Patients in accordance with section 1881(b)(14) (D)(iv)(I) of the Act as follows:

(1) To account for patient age and treatment modality; and

(2) Beginning January 1, 2024, to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during calendar years 2024, 2025, and 2026.

* * * * *

8. Section 413.236 is amended by revising paragraph (b)(2) to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

* * * * *

(b) * * *

(2) Is new, meaning a complete application has been submitted to CMS under paragraph (c) of this section within 3 years of the date of the Food and Drug Administration (FDA) marketing authorization;

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

9. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

10. Section 512.390 is amended by removing paragraph (c)(5) and adding paragraph (d) to read as follows:

§ 512.390 Notification, data sharing, and targeted review.

* * * * *

(d) *Review of targeted review decisions.* The Administrator may review a targeted review request when administrative review is requested by an ETC Participant within 15-calendar days of a targeted review request determination made by CMS.

(1) *Administrative review.* Within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows:

- (i) Decline to review a targeted review request determination made by CMS;
- (ii) Render a final decision based on the CMS Administrator's review of the targeted review request determination; or
- (iii) Choose to take no action on the request for administrative review.

(2) *Administrative review determinations.* The targeted review determination made by the CMS Administrator is final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period described in paragraph (d)(1) of this section.

Dated: June 23, 2023

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2023-13748 Filed: 6/26/2023 4:15 pm; Publication Date: 6/30/2023]